IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant:	Palmaz et al.	Customer No.:	29,335
Serial No.:	09/707,685	Examiner:	C. Miller
Filed:	11/17/2000	Art Unit:	3738
		Confirmation No.:	9696

Title: Endoluminal Stent and Self-supporting Endoluminal Graft and Methods of Making Same

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Lori Dunham

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SUBMISSION OF APPLICANT'S BRIEF ON APPEAL

Dear Sir or Madam:

Applicant submits herewith Applicant's Brief on Appeal. The Commissioner is authorized to deduct the required fee for filing an Appeal Brief in the amount of $335.00 which includes a one month extension fee from Deposit Account 18-2000, of which the undersigned is an authorized user. Accordingly, Applicant does not believe any additional fees are due in the Appeal Brief; however, the Commissioner is authorized to charge any additional fees regarding this filing, and/or credit any overpayment to deposit account No. 18-2000.

APPEAL BRIEF

1. Real Party in Interest

The real party in interest for this patent application is Advanced Bio Prosthetic Surfaces, L.L.C., the assignee of the application.

2. Related Appeals and Interferences

The following appeals have either been decided or are pending in patent applications that are commonly owned with the present application. While applicants do not believe that these pending appeals will directly affect or be directly affected by the Board's decision in the present appeal, applicants disclose these Board decisions and pending appeals due to the common ownership of the patent applications in question.

Board Decision in present application 09/716,146 decided on April 30, 2008, Appeal No. 2007-3212.

Board Decision for related U.S. Application 09/707,685 decided on September 29, 2008, Appeal 2008-1316 (hereinafter the '685 Board Decision").

Board Decision for related U.S. Application 09/783,633 decided on February 21, 2008, Appeal No. 2008-0216.

Board Decision for related U.S. Application 10/672,695 decided on March 31, 2009, Appeal No. 2008-5417.

Board Decision for related U.S. Application 10/258,087 decided on December 20, 2008, Appeal No. 2008-1062

Pending Appeal in U.S. Patent Application Serial No. 09/716,146 to Boyle et al., for Device for In Vivo Delivery of Bioactive Agents and Method of Manufacture Thereof, filed on November 17, 2000. (Attorney Docket No. 6006-018)

Pending Appeal in U.S. Patent Application Serial No. 11/327,795to Boyle et al., for Endoluminal Stent, Self-Supporting Endoluminal Graft and Methods of Making Same, filed on January 6, 2006 (Attorney Docket No. 6006-200)

No decisions have been rendered by a court or by the Board in any of the aforementioned pending appeals identified pursuant to 37 C.F.R. §41.37(c)(ii).

3. Status of Claims

Claims 1-38 and 54-66 have been cancelled. Claims 39-53 and 67-74 are pending and stand rejected under 35 U.S.C. §102(e). The rejection of claims 39-53 and 67-74 is under appeal. Claims 39-53 and 67-74 are set forth in their entirety in Claims Appendix identified below.

4. Status of Amendments

No amendments to the claims were filed after the final rejection.

5. Summary of Claimed Subject Matter

Claims 39, 47, and 67 are independent claims in the pending application. Antecedent support for each element in claims 39, 47, and 67 is noted in the parentheses following each claim element:

Claim 39. A method of manufacturing an endoluminal stent capable of radially expanding from a first diameter to a second diameter (page 16, lines 6-11; page 32, lines 1-2), and having a plurality of first structural elements defining a longitudinal axis of the stent (page 4, lines 7-10; page 5, lines 3-10; page 20, lines 22-24) and a plurality of second structural elements interconnecting adjacent pairs of first structural elements and defining a circumferential axis of the stent (page 4, lines 10-16; page 5, lines 10-15; page 20, lines 24-30), comprising the steps of:

a. vacuum depositing a stent-forming metal onto an unpatterned, exterior surface of a generally cylindrical substrate (page 13, lines 18-29) to form a generally tubular, unpatterned crystalline metal film (page 11, line 30 – page 12, line 4; page 13, lines 6-7) under vacuum deposition process conditions selected to minimize formation of chemical and intra-and intergranular precipitates in the bulk material (page 14, lines 19-29, and the U.S. Patent Application Serial No. 09/443,929, incorporated by reference in the present application and which has subsequently issued as U.S. Patent No. 6,379,383 (the '383 patent"), the '383 patent, col. 7, lines 8-22, *see* Examples 1-4 of the '383 patent);

b. defining the plurality of first and second structural elements of the endoluminal stent in the unpatterned metal film (page 4, lines 5-12; page 13, lines 23-29); and

c. removing the endoluminal stent from the generally cylindrical substrate (page 12, line 29 – page 13, line 5; page 32, line 10).

Claim 47. A method of manufacturing an endoluminal stent capable of radially expanding from a first diameter to a second diameter (page 16, lines 6-11; page 32, lines 1-2),

and having a plurality of first structural elements defining a longitudinal axis of the stent (page 4, lines 7-10; page 5, lines 3-10; page 20, lines 22-24) and a plurality of second structural elements interconnecting adjacent pairs of first structural elements and defining a circumferential axis of the stent (page 4, lines 10-16; page 5, lines 10-15; page 20, lines 24-30), comprising the steps of:

a. vacuum depositing nickel and titanium onto an exterior surface of a generally cylindrical substrate to form an as-deposited generally tubular, crystalline nickel-titanium shape memory film (page 11, line 30 – page 12, line 2; page 14, lines 12-18) having no less than about 51.5 atomic percent nickel (page 11, line 30 – page 12, line 2; page 14, lines 12-18), the vacuum deposition occurring under vacuum deposition process conditions selected to minimize formation of inter- and intra-granular precipitates in the bulk material of the nickel-titanium crystalline film (page 11, line 30 – page 12, line 2; page 14, lines 19-29); and

b. removing the endoluminal stent from the generally cylindrical substrate (page 12, line 29 – page 13, line 5; page 32, line 10).

Claim 67. A method of manufacturing a medical device (page 16, lines 6-11; page 32, lines 1-2), comprising the steps of:

a. vacuum depositing a device-forming metal onto an unpatterned, exterior surface of a generally cylindrical substrate (page 13, lines 18-29) to form a generally tubular, unpatterned crystalline metal film (page 11, line 30 – page 12, line 2; page 14, lines 12-18) under vacuum deposition process conditions selected to substantially eliminate formation of chemical and intra- and intergranular precipitates in the bulk material (page 14, lines 19-29); and

b. removing the deposited generally tubular metal film from the generally cylindrical substrate (page 12, line 29 – page 13, line 5; page 32, line 10).

6. Grounds of Rejection to be Reviewed on Appeal

Whether claims 39-53 and 67-74 are unpatentable under 35 U.S.C. §102(e) over U.S. Patent Application Publication No. 2003/0018381 to *Whitcher* et al. (hereinafter referred to as "*Whitcher*"). For independent Claims 39 and 67, the Examiner alleged in the Final Office Action dated December 7, 2009 the following:

> Referring to claims 39 and 67, Whitcher discloses a method of manufacturing an endoluminal stent (100) capable of radially expanding from a

first diameter to a second diameter and having a plurality of first and second structural elements (see interconnected struts in fig.2 or 3 for example), defining a longitudinal axis and circumferential axis of the stent comprising the steps of vacuum depositing (vacuum deposition is a form of vapor deposition, specifically sputtering and ion beam deposition processes used within a vacuum chamber, which are the same type of vacuum deposition processes used by the applicant, are disclosed by Whitcher, see P0034-P0037) a stent forming metal (120) onto an unpatterned, exterior surface of a generally cylindrical substrate (105) under process conditions (temp, pressure, rate [0035,0036, 0037]) selected (a temp, pressure and rate is disclosed to be selected) to minimize the formation of chemical and intra and inter-granular precipitates in the bulk material of a deposited tubular unpatterned metal crystalline film (115; Whitcher discloses deposition of either an amorphous OR a crystalline film, see P0038-P0040, P0043, P0049, P0061, example l), defining the plurality of first and second structural elements of the stent in the unpatterned metal film, and removing the stent from the substrate [0051,0052, 0053].

Referring back to the limitation, process condition "selected to minimize" granular precipitates, granular precipitates are categorized in the applicant's specification as one of the many "material properties" that are collectively controlled by deposition, see pg. 10, lines 12-16. The applicant's specification discloses that the collection of material properties, including the granular precipitates, are controlled or minimized by the actual deposition process, see pg. 11, lines 11-15; pg.11 line 30-pg.12, line 2; pg.12, lines 11-13; pg.14, lines 1-12, 19-21. That is, Applicant's disclosure points simply to a vacuum deposition process (sputtering and ion-beam evaporation; pg. 11, lines 1 1-24) as the means for minimizing precipitates and other material properties. Although Whitcher does not explicitly recite granular precipitates, Whitcher does disclose use of the same vacuum deposition processes (sputtering, ion beam deposition, etc., P0034-P0037) and the use of the same materials used by the applicant (P0062) therefore, and discloses such processes control material properties (P0011, P0028), inherently Whitcher is controlling and minimizing material properties such as granular precipitates just as much as the applicants are.

Further, Whitcher specifically discloses accurately and precisely controlling the composition and microcrystal structure to have the desired mechanical properties [P0011,0028, 0038, 0042, 0043], therefore, inherently the granular precipitates are controlled, since granular precipitates are an element of a materials microstructure and the material's mechanical properties, the microstructure and properties which are disclosed to be controlled.

Additionally, Whitcher discloses selection of a process condition. Whitcher discloses selection of a temperature, pressure, and rate during deposition, therefore, inherently the precipitates are being controlled, since amount and size of the granular precipitates are dependent upon temp, pressure, and rate (general process conditions of vacuum deposition, which applicant has disclosed to be the method of minimizing precipitates), and upon selection of these conditions, one has controlled the crystal structure outcome of the metal, hence controlled how

much formation of precipitates has occurred. Because Whitcher has disclosed a temperature, pressure, and rate, hence the material properties are preselected and are being controlled by the selection. Also, every metal has a specific granular makeup, including precipitates, and just by the user selecting a specific material to be deposited, the user is controlling the grain size, grain phase, granular precipitates, composition, and binding sites etc.

Further, applicant noted in their previous arguments, inherently precipitates are formed in all post treatments such as annealing. Since some of Whitcher's methods disclose depositing a crystalline film, without the use of annealing process, no precipitates would be formed in the first place, thus are already minimized, since no annealing has taken place and the deposited film is crystalline.

Also, applicant has claimed "process conditions selected to minimize formation of chemical and intra and inter-granular precipitates", however they have not claimed to what extent (numerical value) such properties are minimized to. No numerical amount has been assigned to "minimized". It is vague and arbitrary what amount "minimize" is and how it should be examined. It is unclear how to interpret such a word, with no exact value. As best as can be interpreted, Whitcher is believed to have "minimized" formation of precipitates, since the disclosed film may be crystalline upon deposition, since crystalline, would have no precipitates.

Final Office Action dated December 7, 2009, pp. 7-10.

The Examiner alleges the same argument for independent claim 47.

7. Argument

I. The Examiner's anticipation rejection of claims 39-53 and 67-74 under 35 U.S.C. § 102(e) over *Whitcher* is improper and should be withdrawn.

For a prior art reference to anticipate a claim, the prior art reference must teach every element of the claim. *See* MPEP §2131; *see also Richardson v. Suzuki Motor Co.*, 868 F.2d 1226. 1236 (Fed. Cir. 1989) (holding that "[t]he identical invention must be shown in as complete detail as is contained in the...claim." [Emphasis added].); *see also Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987) (stating that anticipation requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference"). Additionally, while an identity of terminology is not required, the elements must nonetheless be arranged as required by the claim. *See In re Bond*, 910 F.2d 831, 832-833 (Fed. Cir. 1990) (holding that anticipation can not be established by mere equivalents).

The claimed invention is generally directed toward a method for manufacturing an endoluminal stent comprising, *inter alia*, the step of vacuum depositing a stent-forming metal onto a substrate under process conditions selected to minimize (or substantially eliminate) formation of chemical and intra- and inter-granular precipitates in the bulk material. The Examiner has failed to establish that *Whitcher* anticipates the claims on appeal because *Whitcher* does not teach, expressly or implicitly, the step of vacuum depositing a stent-forming metal onto a substrate under process conditions selected to minimize (or substantially eliminate) formation of chemical and intra- and inter-granular precipitates in the bulk material. Applicants submit that independent claims 39, 47, and 67, and claims dependent therefrom, specifically dependent claims 40, 41, 42, 43, 44, 45, 46, 48, 49, 50, 51, 52, 53, 68, 69, 70, 71, 72, 73, and 74, are patentable over the prior art cited and of record.

a. *Any deposited amorphous or crystalline film in Whitcher does not mean or include minimized precipitates according to one of ordinary skill in the art*

The Board Decision in present application 09/707,685 decided on September 29, 2008, Appeal 2008-1316 (hereinafter the '685 Board Decision") stated that Whitcher explicitly describes deposition of monocrystalline and nanocrystalline metallic films (Board Decision, FF 15). In the Final Office Action dated December 7, 2009, the Examiner alleged Whitcher discloses:

> [S]teps of vacuum depositing (vacuum deposition is a form of vapor deposition, specifically sputtering and ion beam deposition processes used within a vacuum chamber, which are the same type of vacuum deposition processes used by the applicant, are disclosed by Whitcher, see P0034-P0037) a stent forming metal (120) onto an unpatterned, exterior surface of a generally cylindrical substrate (105) under process conditions (temp, pressure, rate [0035,0036, 00371) selected (a temp, pressure and rate is disclosed to be selected) to minimize the formation of chemical and intra and inter-granular precipitates in the bulk material of a deposited tubular unpatterned metal crystalline film (115; Whitcher discloses deposition of either an amorphous OR a crystalline film, see P0038-P0040, P0043, P0049, P0061, example l)…

Final Office Action dated December 7, 2009, p. 8. An amorphous film or a crystalline film does not include or encompass minimized chemical and intra and inter-granular precipitates. The *Whitcher* reference does not define the term "precipitate" anywhere in the specification. Applicant sought to define "crystalline" (nanocrystalline and monocrystalline) in the Request for Continued Examination dated August 17, 2009, as to clearly distinguish "crystalline" from "precipitates" for the Examiner as one of ordinary skill in the art would interpret such terms.

The term "nanocrystalline" is undefined in *Whitcher*; however, it is generally understood to simply be nano-scale polycrystalline structures. (*See, e.g.*, Hollister, P., et al., Nanocrystalline Materials, Technology White Papers nr. 4, Cientifica, Oct. 2003, nanotechweb.org/dl/wp/nanocrystalline_materials_WP.pdf, a copy of which is attached as Exhibit A and previously submitted in Applicant's Request for Continued Examination dated August 17, 2009). The term "monocrystalline" is also undefined in *Whitcher*. However, "monocrystalline" is generally understood to mean "formed of a single crystal-unit, and so all elements have identical crystallographic orientation of c- and a-axes and overgrow as one unit." (*See*, <www.nhm.ac.uk/hosted_sites/ina/terminology/7crystallography.htm>, last accessed June 8, 2010.) Monocrystalline (a/k/a single crystal) materials as taught by *Whitcher* are drawn filaments and are not, therefore, vacuum deposited onto a cylindrical substrate to form a tubular film structure with minimized precipitates. And Whitcher describes nano-scale crystal structures as desirable to enhance mechanical properties of the medical device, which does not speak to minimized precipitation formation. Whitcher, ¶ [0038]-[0040].

As widely known to those skilled in the metallurgical arts, the term "precipitate[1]", as it pertains to fabrication of biomaterials and with particular reference to nickel-titanium shape memory alloys, means reaction products formed from a solid solution under increased thermal conditions which drive the precipitate from solution, resulting in formation of the reaction products outside the solid solution, *i.e.*, outside the metal crystalline structure. An excellent monograph on precipitation reactions in nickel-titanium binary shape memory alloy systems is found at Pelton, A.R., et al., Optimisation of processing and properties of medical grade Nitinol Wire, *Min Invas Ther & Allied Techno.*, 2000: 9(1) 107–118, Published: 2001, a copy of which is attached as Exhibit B and previously submitted in Applicant's Request for Continued Examination dated September 1, 2009. Pelton is related to cold-work and heat treatment of nitinol and shows that precipitates of nitinol that include $Ti_{11}Ni_{14}$, Ti_2Ni_3, and $TiNi_3$. Pelton, p. 113. Precipitates are formed during the increased thermal conditions of vacuum deposition techniques, i.e. heating a source material to a temperature to cause vaporization thereof for evaporization, or ionizing metals that collide with gas atoms and dislodge source material as in sputtering deposition, or using high energy beam of metals by ionizing a source material as in

[1] Online website <www.dictionary.com> defines the term precipitate as "a substance precipitated from a solution" and "to separate (a substance) in solid form from a solution, as by means of a reagent."

ion beam assisted deposition. As such, one of ordinary skill in the art would not equate nanocrystalline or monocrystalline with precipitates, as precipitates themselves are outside the metal crystalline structure.

Finally, Whitcher describes an amorphous film as the crystallization of structures formed with an amorphous morphology and an amorphous metallic structure may be deposited onto a substrate. Since the amorphous film is directed to the crystalline structure of the metallic film, it is not pertain to or relevant to "precipitates", i.e. reaction products formed from a solid solution under increased thermal conditions which drive the precipitate from solution, resulting in formation of the reaction products outside the solid solution, *i.e.*, outside the metal crystalline structure, such as $Ti_{11}Ni_{14}$, Ti_2Ni_3, and $TiNi_3$. As such, any amorphous film in Whitcher does not include or encompass minimized chemical and intra and inter-granular precipitates. For at least these reasons, applicants submit that pending claims 39-53 and 67-74 are distinguished from and patentable over the prior art cited and of record.

b. *Examiner cannot use the Applicant's own specification to support any anticipation or inherency argument, rationale, or fact*

The Examiner alleged the following with respect to process condition selected to minimize granular precipitates:

> [G]ranular precipitates are categorized in the applicant's specification as one of the many "material properties" that are collectively controlled by deposition, see pg. 10, lines 12- 16. The applicant's specification discloses that the collection of material properties, including the granular precipitates, are controlled or minimized by the actual deposition process, see pg. 11, lines 11-15; pg.11 line 30-pg.12, line 2; pg.12, lines 11-13; pg.14, lines 1-12, 19-21. That is, Applicant's disclosure points simply to a vacuum deposition process (sputtering and ion-beam evaporation; pg. 11, lines 1 1-24) as the means for minimizing precipitates and other material properties. Although Whitcher does not explicitly recite granular precipitates, Whitcher does disclose use of the same vacuum deposition processes (sputtering, ion beam deposition, etc., P0034-P0037) and the use of the same materials used by the applicant (P0062) therefore, and discloses such processes control material properties (P0011, P0028), inherently Whitcher is controlling and minimizing material properties such as granular precipitates just as much as the applicants are.

Final Office Action dated December 7, 2009, p. 8-9. The Examiner must determine whether the subject matter identified as "prior art" is applicant's own work, or the work of another. MPEP § 2129. It would <u>not</u> be appropriate for the Examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well known are

not capable of instant and unquestionable demonstration as being well-known. MPEP § 2144.03. For example, assertions of technical facts in the areas of esoteric technology or specific knowledge of the prior art must always be supported by citation to some reference work recognized as standard in the pertinent art. *In re Ahlert*, 424 F.2d at 1091, 165 USPQ at 420-21, MPEP § 2144.03. The Applicant vehemently objects to the Examiner using the Applicant's own specification for any rationale and reasoning to support an anticipation or inherency argument for Whitcher's vacuum deposition processes selected to minimize the formation of intra and inter-granular precipitates. The Examiner's use of Applicant's own specification is the best example of hindsight reasoning by the Examiner, and more importantly, nothing in the Applicant's specification has identified the vacuum deposition steps selected minimize the formation of intra and inter-granular precipitates as prior art. The Applicant respectfully requests the Board to ignore the Examiner's use of the Applicant's own specification to support the Examiner's §103(a) reasoning or official notice of such fact. The Examiner's noticed fact of "collection of material properties, including the granular precipitates, are controlled or minimized by the actual deposition process" is not considered to be common knowledge or well-known in the art. Moreover, any teaching of general vacuum deposition in Whitcher is not enough for one of ordinary skill in the art, and specific parameters and vacuum deposition steps are disclosed in the Applicant's specification to minimize the formation of precipitates, none of which are disclosed in Whitcher. As the Applicant will explain more fully below, the teachings in Whitcher does not minimize the formation of inter and intragranular precipitates, and any inherency threshold cannot be overcome by using or relying on the teachings of Applicant's disclosure for minimizing precipitates. For at least these reasons, applicants submit that pending claims 39-53 and 67-74 are distinguished from and patentable over the prior art cited and of record.

c. Whitcher is not "inherently controlling and minimizing material properties such as granular precipitates just as much as applicants are."

In the Final Office Action dated December 7, 2009, the Examiner alleged:

> [G]ranular precipitates are categorized in the applicant's specification as one of the many "materials properties" that are collectively controlled by deposition, see pg. 10, lines 12-16. The applicant's specification discloses that the collection of material properties, including the granular precipitates, are controlled or minimized by the actual deposition process, see pg. 11, lines 11-15, pg.11 line 30 – pg.12, line 2; pg.12, lines 11-13; pg.14, lines 1-12, 19-21. That is, Applicant's disclosure points simply to a vacuum deposition process (sputtering and ion beam evaporation, pg.11, lines 11-24) as the means for minimizing precipitates and

> other material properties. Although Whitcher does not explicitly recite granular precipitates, Whitcher does disclose the use of the same vacuum deposition processes (sputtering, ion beam deposition, etc., P0034-P0037) and the use of the same materials used by the applicant (P0062) therefore, and discloses such processes control material properties (P0011, P0028), inherently Whitcher is controlling and minimizing material properties such as granular precipitates just as much as the applicants are.

Final Office Action dated December 7, 2009, p. 8-9.

Contrary to the Examiner's contention, Whitcher does not teach "inherently controlling and minimizing material properties such as granular precipitates just as much as the applicants are." First, applicants assert that granular precipitates are not categorized as one of the many "materials properties" that are *collectively* controlled by deposition, as the Examiner contends. [Emphasis added]. With respect to the definition of "materials properties" applicants' specification recites:

> The term "material properties" is intended to encompass physical properties, including without limitation, elasticity, tensile strength, mechanical properties, hardness, bulk and/or surface grain size, grain composition, and grain boundary size, intra and inter-granular precipitates.

Present Application, p. 10, Lines 12-16.

The specification does not disclose that all of the listed properties are collectively controlled by deposition. Rather, as the applicants state in the specification, the "desired material properties" are controlled by vacuum deposition process conditions. *See* Specification at 11, Line 9. Applicants' listing of the physical properties that encompass "material properties" is simply a list of properties that may be controlled. All properties of a material are not cooperatively controlled or controlled as a group by deposition. For example, the process conditions selected to increase hardness are not the same process conditions selected to increase elasticity or the same process conditions selected to set a transition temperature.

Moreover, applicants do not simply point to a vacuum deposition process as the means for minimizing precipitates and other material properties. First, if it was true that merely using vacuum deposition minimizes precipitates, then the annealing step in the prior art vacuum deposition processes would have been unnecessary, as that step was introduced in order to drive out the precipitates formed during deposition. The applicants' specification states that its inventive process does not form precipitates and, hence, eliminates the need for a post-processing annealing step. Second, if it was true that the deposition process alone controlled the

material properties, as the Examiner suggests, then all of the material properties would be *collectively* minimized or controlled simply by using the vacuum deposition process. As discussed above, this is untrue. Finally, applicants' vacuum deposition process conditions are selected to minimize (or substantially eliminate) *the formation of* granular precipitates. Applicants' inventive method does not merely reduce the size of precipitates (minimize precipitates) as suggested by the Examiner, rather the method prevents the formation of precipitates. Thus, applicants' disclosure does not simply point to a vacuum deposition process as the means for minimizing precipitates and other material properties.

Further, the Examiner contends that because *Whitcher* discloses use of the same vacuum deposition process (sputtering, ion beam, etc.), use of the same materials, and that deposition processes control material properties, then *Whitcher* inherently controls granular precipitates. This reasoning is flawed. First, applicants submit that it is not sufficient for the Examiner to base an anticipation rejection relying on inherency on broad generalizations regarding the prior art. The Examiner has failed to provide any disclosure in *Whitcher* that clearly and specifically provides the elements of the claims on appeal, either expressly or inherently. Second, as discussed above, the "material properties" are not collectively controlled by the deposition process. Finally, by way of analogy, the Examiner argues that to make a cookie, if one discloses use of the same cooking process (i.e. an oven, stove, microwave), use of the same ingredients, and that the oven controls cookie properties, then the softness of the cookie is inherently controlled or the color of the cookie is inherently controlled. Any lay person reading this would recognize the severe flaw in logic. There are process conditions that would directly influence the resulting properties of the cookie such as the cooking time, temperature, placement in the oven (height and lateral distance from heat source), or the baking surface. A change in any of these conditions could affect the softness or color of the cookie. Thus, using the same process and materials cannot render a property inherent, and more fully explained with respect to vacuum depositions below.

The '685 Board Decision stated that no working examples or specific vacuum deposition conditions are described in the Specification (FF8). The Applicant previously indicated in the Request for Continued Examination filed August 17, 2009 that the present application states the following:

> As is described in co-pending, commonly assigned, U.S. Patent Application Serial No. 09/443,929, filed November 19, 1999, which is hereby incorporated by reference, heterogeneities are controlled by fabricating the bulk material of the stent to have defined grain sizes, chemical and intra and intergranular precipitates and where the bulk and surface morphology differ, yielding areas or sites along the surface of the stent while maintaining acceptable or optimal protein binding capability.

Present Application, p. 10, lines 24-30. So the present application indicates that chemical and intra- and intergranular precipitates are controlled by the vacuum deposition processes disclosed in U.S. Patent Application Serial No. 09/443,929. The present application also further states that when sputtering techniques are employed, a 200 micron thick stainless steel film may be deposited within about four hours of deposition time and it is preferable to employ a cylindrical sputtering target, a single circumferential source that concentrically surrounds the substrate that is held in a coaxial position within the source. Present Application, p. 11, lines 24-28. The U.S. Patent Application Serial No. 09/443,929 has subsequently issued as U.S. Patent No. 6,379,383 (the '383 patent") and the '383 patent discloses several working examples of sputtering a stainless steel film with a circumferential deposition source, whereby specific vacuum deposition conditions control the surface properties of the deposited metal film characterized by controlled heterogeneities in grain size, material composition and surface topography. See e.g. Examples 1-4 of the '383 patent. Such vacuum deposition conditions disclosed in the '383 patent are remarkably different than Whitcher, which include the following—the ceramic substrate has capabilities of glow discharge cleaning, pre-cleaning the substrates under vacuum by glow discharge, the substrate temperature between about 300 and 110 degrees and bias voltage between -1000 and +1000 volts for sputtering, deposition sources are circumferential and oriented to deposited from the target circumferentially about the substrate. The '383 patent, col. 7, lines 8-22. Whitcher does not teach or disclose such vacuum deposition conditions and the Examiner inappropriately ignores these specific vacuum deposition process parameters and steps in any comparison with Whitcher for teaching or enabling the vacuum deposition conditions selected to minimize the formation of chemical and intra- and inter-granular precipitates in the bulk material. As such, the present application supports vacuum deposition conditions to minimize (or substantially eliminate) formation of chemical and intra- and inter-granular precipitates in the bulk material of the as deposited crystalline film, and Whitcher fails to anticipate such limitations in claims 39-53 and 67-74.

Finally, any removal of impurities by Whitcher is for the purpose of filtering particular isotopes and disclosed in Whitcher for ion beam assisted deposition and not for the purposes of minimizing precipitates. Whitcher discloses that ion beam assisted deposition uses a filter to separate different mass-weight species that is targeted at the substrate, which separate isotopes of an element and direct a particular isotope to the substrate. Whitcher, ¶ 0037. Whitcher gives an example of titanium with an atomic weight of 48 may be selected for vapor deposition, while rejecting titanium with atomic weights of 46, 47, 49, and 50, or oxygen may be filtered away from the substrate. *Id.* Such filtering methods for impurities in Whitcher is not for the purposes, nor enables, the minimization of precipitates which are formed on the substrate as deposited metals, i.e. precipitates are formed during the increased thermal conditions of vacuum deposition techniques such as $Ti_{11}Ni_{14}$, Ti_2Ni_3, and $TiNi_3$. As such, any removal of impurities by Whitcher is for the purpose of filtering particular isotopes and disclosed in Whitcher for ion beam assisted deposition and not for the purposes of minimizing precipitates.

For at least these reasons, applicants submit that pending claims 39-53 and 67-74 are distinguished from and patentable over the prior art cited and of record.

d. *Whitcher* does not disclose *accurately and precisely controlling* the formation of granular precipitates.

According to the Examiner in the Final Office Action mailed on December 7, 2009:

> Further, Whitcher specifically discloses accurately and precisely controlling the composition and microcrystal structure to have the desired mechanical properties [P0011, 0028, 0038, 0042, 0043], therefore, inherently the granular precipitates are controlled, since granular precipitates are an element of a materials microstructure and the material's mechanical properties, the microstructure and properties which are disclosed to be controlled.

Final Office Action dated December 7, 2009, p. 9. Contrary to the Examiner's contention, *Whitcher* does not "*accurately and precisely*" control the formation of granular precipitates. A review of the paragraphs cited by the Examiner reveals that they fail to support the Examiners' conclusions.

The Examiner cites paragraph 0038 of *Whitcher* to support the argument that granular precipitates are accurately and precisely controlled in *Whitcher*. In paragraphs 0037 and 0038, *Whitcher* teaches removing impurities from the metal material. Paragraph 0038 of *Whitcher* states, in relevant part, "[t]he removal of impurities and the filtering of particular isotopes are useful in the present invention." Applicants assert that removing impurities as taught by

Whitcher is not the same as preventing the formation of precipitates as claimed by applicants. [Emphasis added]. Impurity or foreign atoms will always be present in any metal, even if it is considered pure. Most familiar metals are alloys in which impurity atoms have been added intentionally to impart specific characteristics to the material. The addition of impurity atoms to a metal will result in the formation of a solid solution. A solid solution consists of atoms of at least two different types; the solute atoms occupy either substitutional or interstitial positions in the solvent lattice; and the crystal structure of the solvent is maintained. The reaction products formed from a solid solution under increased thermal conditions in vacuum deposition are precipitates; they are driven from the solid solution resulting in the formation of the reaction products outside the solid solution, i.e. the metal crystalline structure.

The difference between removing impurities as taught by *Whitcher* and preventing the formation of precipitates as claimed by applicants is blatantly clear with respect to metal alloys. Removing impurities from a metal alloy may result in removing impurity atoms that were intentionally added, which would likely result in less desired characteristics of the material. Preventing the formation of precipitates in a metal alloy, on the other hand, would not remove any impurity atoms that were intentionally added, but would prevent solid solution reaction products from forming under increased thermal conditions during vacuum deposition. Thus, with respect to alloys, removing impurities as taught by *Whitcher* is not the same as preventing the formation of precipitates as claimed by applicants. Furthermore, removing impurities from any metal would not necessarily prevent the formation of precipitates because impurity atoms will always be present, thus a solid solution and increased thermal conditions would present an opportunity for precipitate formation.

The Examiner also cites paragraphs 0042 and 0043 of *Whitcher* to support the argument that granular precipitates are accurately and precisely controlled in *Whitcher*. Paragraph 0043 makes clear that "[s]uch nanocrystalline structures can be formed by depositing an amorphous layer of desired material onto a substrate or target. The above-described aging techniques (annealing) can be used to form nanometer sized crystals." It is manifestly and unequivocally clear that *Whitcher* teaches depositing a material onto a substrate in its amorphous state and after deposition treating or aging the amorphous structure (as expressly taught in paragraph 0041) to form either a monocrystalline or nanocrystalline structure. This is, without question, different

and distinct from the presently claimed invention wherein a film is vacuum deposited as a crystalline layer onto the substrate under conditions which minimize precipitate formation.

In addition, the Examiner relies on Paragraph 0028 of *Whitcher* that states, in relevant part, that "[b]y using vapor deposition techniques for the formation of medical devices, the composition, thickness, surface roughness, and microstructures of devices formed in accordance with the present invention are accurately and precisely controlled." [Emphasis added]. It is clear from the Examiner's cited paragraphs that the devices formed in accordance with *Whitcher*'s invention are formed from either (1) single crystal or monocrystalline materials or (2) nanocrystalline materials made by annealing an amorphous layer.

In paragraphs 0038, 0039, and 0040, *Whitcher* discloses forming medical devices made of single crystal or monocrystalline materials or forming a single crystal filament that is used as a substrate in a vapor deposition process to make a monocrystalline medical article. A single crystal results when the periodic and repeated arrangement of atoms is perfect or extends throughout the entirety of the specimen without interruption. Thus, a single crystal or monocrystalline material is one in which the arrangement of atoms is perfect or extends throughout the entirety of the specimen without interruption. In the aforementioned paragraphs, *Whitcher* only discloses forming medical devices from single crystal or monocrystalline materials. Paragraphs 0042 and 0043 both refer to medical devices made of nanocrystalline materials that were made by annealing an amorphous layer. *Whitcher* therefore discloses accurately and precisely controlling the microstructures of the devices made from either (1) single crystal or monocrystalline materials or (2) nanocrystalline materials made by annealing an amorphous layer. Applicants' devices, however, are not fabricated from the aforementioned materials, thus *Whitcher* does not teach accurately and precisely controlling their microstructures as contended by the Examiner.

For at least these reasons, applicants submit that pending claims 39-53 and 67-74 are distinguished from and patentable over the prior art cited and of record.

e. *Whitcher's selection of a process condition does not inherently minimize precipitates*

According to the Examiner in the Final Office Action mailed on December 7, 2009:

> Additionally, Whitcher discloses selection of a process condition. Whitcher discloses selection of a temperature, pressure, and rate during deposition, therefore, inherently the precipitates are being controlled, since amount and size of the granular precipitates are dependent upon temp, pressure, and rate (general

> process conditions of vacuum deposition, which applicant has disclosed to be the method of minimizing precipitates), and upon selection of these conditions, one has controlled the crystal structure outcome of the metal, hence controlled how much formation of precipitates has occurred. Because Whitcher has disclosed a temperature, pressure, and rate, hence the material properties are preselected and are being controlled by the selection. Also, every metal has a specific granular makeup, including precipitates, and just by the user *selecting* a specific material to be deposited, the user is *controlling* the grain size, grain phase, granular precipitates, composition, and binding sites etc.

Final Office Action, dated December 7, 2009 p. 9.

Applicants submit that it is not sufficient for the Examiner to base an anticipation rejection relying on inherency on broad generalizations regarding the prior art.

> "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)

See MPEP §2112.

The Examiner has failed to provide any disclosure in *Whitcher* that clearly and specifically provides the elements of the claims on appeal, either expressly or inherently. Applicants respectfully assert that *Whitcher* merely states conditions selected, *i.e.*, chamber pressure, deposition rate, without any suggestion that those conditions may be controlled in such a manner as to minimize precipitate formation in a crystalline film or even that a crystalline film is formed as a result of the specific selected conditions. In fact, none of the Examples found in *Whitcher* contain any statement or suggestion that the vacuum deposited film is crystalline, or that precipitate formation is, in fact, controlled. Moreover, applicants submit that the Examiner has not explained, by presenting a preponderance of evidence, or any evidence, why a person of ordinary skill in the art would recognize that the allegedly inherent characteristic necessarily flows from the teachings of *Whitcher*. To the extent that the Examiner's opinion is based on her personal knowledge, applicant requests under 37 C.F.R. §1.104(d)(2) that Examiner provide such information specifically and with support by a reference, all presented by affidavit of the Examiner.

For at least these reasons, applicants submit that pending claims 39-53 and 67-74 are distinguished from and patentable over the prior art cited and of record.

f. *Process conditions selected to minimize formation of chemical and intra and inter-granular precipitates is not vague and arbitrary and the Examiner has not properly considered the limitation*

According to the Examiner in the Final Office Action mailed on December 7, 2009:

> [A]pplicant has claimed "process conditions selected to minimize formation of chemical and intra and inter-granular precipitates", however they have not claimed to what extent (numerical value) such properties are minimized to. No numerical amount has been assigned to "minimized". It is vague and arbitrary what amount "minimize" is and how it should be examined. It is unclear how to interpret such a word, with no exact value. As best as can be interpreted, Whitcher is believed to have "minimized" formation of precipitates, since the disclosed film may be crystalline upon deposition, since crystalline, would have no precipitates.

Final Office Action dated December 7, 2009, p. 10. The Examiner complains that "minimize" is vague and arbitrary; however, the Examiner has not rejected Claim 39 on any basis under 35 U.S.C. §112, second paragraph for indefiniteness. More so, a claim limitation which is considered indefinite cannot be disregarded. MPEP § 2143.03. The reaction products formed from a solid solution under increased thermal conditions of vacuum deposition are precipitates; they are driven from the solid solution resulting in the formation of the reaction products outside the solid solution, i.e. the metal crystalline structure. Minimizing the formation of precipitates in a metal alloy minimizes the solid solution reaction products from forming under increased thermal conditions during vacuum deposition. "Minimize" generally means "reduce or keep to a minimum". (www.merriam-webster.com, last accessed May 6, 2010.) Thus, the claim term "minimize intra- and inter-granular precipitates" would generally mean reduce or keep the precipitates to a minimum. The Examiner's confusion of "minimize" belies the Examiner's point that Whitcher's vacuum deposition process is selected to minimize formation of chemical and intra and inter-granular precipitates, as the Examiner has not properly construed the limitation "process conditions selected to minimize formation of chemical and intra and inter-granular precipitates"; thus how can the Examiner properly conclude that Whitcher selects any vacuum deposition process conditions to minimize the formation of precipitates. Therefore, the process conditions selected to minimize formation of chemical and intra and inter-granular precipitates is not vague and arbitrary, and the Examiner has not properly considered the "vacuum deposition process is selected to minimize formation of chemical and intra and inter-

granular precipitates", and Whitcher fails to anticipate the limitation according to the Examiner's rationale.

For at least these reasons, applicants submit that pending claims 39-53 and 67-74 are distinguished from and patentable over the prior art cited and of record.

Conclusion

An anticipation rejection under 35 U.S.C. §102(e) requires that the cited prior art reference must disclose each and every claimed element. *Whitcher* does not teach or suggest every limitation recited in the pending claims on appeal. More specifically, *Whitcher* fails to teach a method of manufacturing an endoluminal stent comprising the step of vacuum depositing a stent-forming metal onto a substrate under process conditions selected to minimize (or substantially eliminate) formation of chemical and intra- and inter-granular precipitates in the bulk material. Furthermore, *Whitcher* does not enable the teachings for which the Examiner relies on *Whitcher*. Thus, *Whitcher* does not anticipate the pending claims on appeal, and the Examiner's anticipation rejection is improper and should be withdrawn.

Accordingly, applicant respectfully requests that the Board withdraw the 35 U.S.C. §102(e) rejection of claims 39-53 and 67-74, and allow the above-identified application to proceed to allowance and issuance.

Respectfully submitted,

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June 8, 2010

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8. Claims Appendix

The following is a listing of the claims on appeal.

Claims 1-38. (Cancelled)

Claim 39. A method of manufacturing an endoluminal stent capable of radially expanding from a first diameter to a second diameter, and having a plurality of first structural elements defining a longitudinal axis of the stent and a plurality of second structural elements interconnecting adjacent pairs of first structural elements and defining a circumferential axis of the stent, comprising the steps of:

a. vacuum depositing a stent-forming metal onto an unpatterned, exterior surface of a generally cylindrical substrate to form a generally tubular, unpatterned crystalline metal film under vacuum deposition process conditions selected to minimize formation of chemical and intra- and intergranular precipitates in the bulk material;

b. defining the plurality of first and second structural elements of the endoluminal stent in the unpatterned metal film; and

c. removing the endoluminal stent from the generally cylindrical substrate.

Claim 40. The method according to Claim 39, further comprising a step of depositing a sacrificial material layer onto the substrate prior to step (a) and removing the sacrificial material layer in order to remove the endoluminal stent from the substrate in step (c).

Claim 41. The method according to Claim 39, wherein step (a) is conducted by ion beam-assisted evaporative deposition.

Claim 42. The method according to Claim 39, wherein step (a) is conducted by sputtering.

Claim 43. The method according to Claim 41, wherein the ion beam-assisted evaporative deposition is conducted in the presence of an inert gas.

Claim 44. The method according to Claim 43, wherein the inert gas is selected from the group consisting of argon, xenon, nitrogen and neon.

Claim 45. The method according to Claim 39, wherein the process condition controlled is deposition rate and the deposition rate is no less than about 20 nm/sec.

Claim 46. The method according to Claim 39, wherein during the deposition of the stent-forming metal, the substrate is rotated.

Claim 47. A method of manufacturing an endoluminal stent capable of radially expanding from a first diameter to a second diameter, and having a plurality of first structural elements defining a longitudinal axis of the stent and a plurality of second structural elements interconnecting adjacent pairs of first structural elements and defining a circumferential axis of the stent, comprising the steps of:

a. vacuum depositing nickel and titanium onto an exterior surface of a generally cylindrical substrate to form an as-deposited generally tubular, crystalline nickel-titanium shape memory film having no less than about 51.5 atomic percent nickel, the vacuum deposition occurring under vacuum deposition process conditions selected to minimize formation of inter- and intra-granular precipitates in the bulk material of the nickel-titanium crystalline film; and

b. removing the endoluminal stent from the generally cylindrical substrate.

Claim 48. The method according to Claim 47, wherein the generally tubular film of nickel-titanium has a composition of between about 51.5 and about 55.0 atomic percent nickel.

Claim 49. The method according to Claim 47, wherein during the deposition of the nickel and titanium, the substrate is rotated.

Claim 50. The method according to Claim 47, wherein a source of the nickel and the titanium to be deposited is a nickel-titanium alloy.

Claim 51. The method according to Claim 47, wherein a source of the nickel and the titanium to be deposited is a binary nickel-titanium alloy.

Claim 52. The method according to Claim 47, further comprising, prior to step (a), a step of imparting a pattern defining the first and second structural elements onto the exterior surface of the substrate, and wherein the pattern is transferred to the tubular film of nickel-titanium during step (a).

Claim 53. The method according to Claim 47, further comprising a step of imparting a pattern defining the first and second structural elements onto the tubular film of nickel-titanium after step (a).

Claims 54-66. (Cancelled)

Claim 67. A method of manufacturing a medical device, comprising the steps of:

a. vacuum depositing a device-forming metal onto an unpatterned, exterior surface of a generally cylindrical substrate to form a generally tubular, unpatterned crystalline metal film under vacuum deposition process conditions selected to substantially eliminate formation of chemical and intra- and intergranular precipitates in the bulk material; and

b. removing the deposited generally tubular metal film from the generally cylindrical substrate.

Claim 68. The method according to Claim 67, further comprising a step of depositing a sacrificial material layer onto the substrate prior to step (a) and removing the sacrificial material layer in order to remove the endoluminal stent from the substrate in step (b).

Claim 69. The method according to Claim 67, wherein step (a) is conducted by ion beam-assisted evaporative deposition.

Claim 70. The method according to Claim 67, wherein step (a) is conducted by sputtering.

Claim 71. The method according to Claim 69, wherein the ion beam-assisted evaporative deposition is conducted in the presence of an inert gas.

Claim 72. The method according to Claim 71, wherein the inert gas is selected from the group consisting of argon, xenon, nitrogen and neon.

Claim 73. The method according to Claim 67, wherein the process condition controlled is deposition rate and the deposition rate is no less than about 20 nm/sec.

Claim 74. The method according to Claim 67, wherein during the deposition of the device-forming metal, the substrate is rotated.

9. Evidence Appendix

Exhibit A: Hollister, P., et al., Nanocrystalline Materials, Technology White Papers nr. 4, Cientifica, Oct. 2003, nanotechweb.org/dl/wp/nanocrystalline_materials_WP.pdf,) a copy which was previously submitted in Applicant's Request for Continued Examination dated August 17, 2009.

Exhibit B: Pelton, A.R., et al., Optimisation of processing and properties of medical grade Nitinol Wire, *Min Invas Ther & Allied Techno.*, 2000: 9(1) 107–118, Published: 2001, a copy which was previously submitted in Applicant's Request for Continued Examination dated August 17, 2009.

10. Related Proceedings Appendix

Copies of Board Decision in present application 09/707,685 decided on September 29, 2008, Appeal 2008-1316 (hereinafter the '685 Board Decision"), Board Decision for related U.S. Application 09/716,146 decided on April 30, 2008, Appeal No. 2007-3212, Board Decision for related U.S. Application 09/783,633 decided on February 21, 2008, Appeal No. 2008-0216, Board Decision for related U.S. Application 10/672,695 decided on March 31, 2009, Appeal No. 2008-5417, and Board Decision for related U.S. Application 10/258,087 decided on December 22, 2008, Appeal No. 2008-1062, are attached herewith.

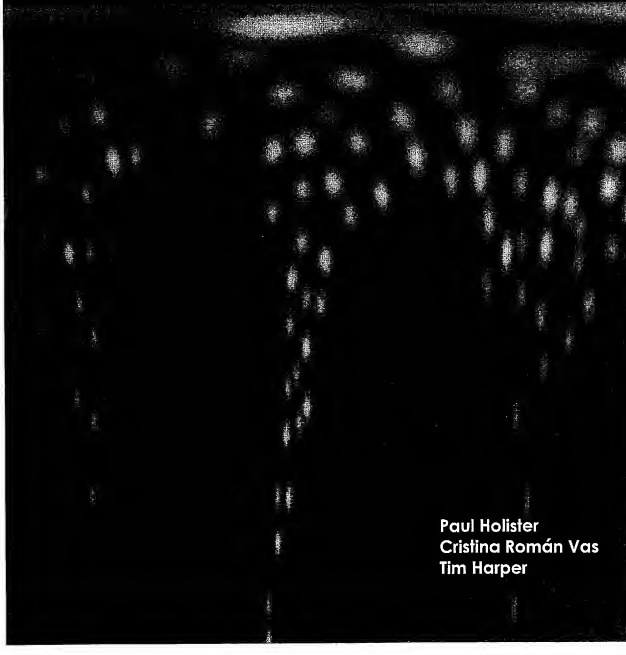
No decisions have been rendered by a court or by the Board in any of the pending appeals identified under Related Appeals and Interferences pursuant to 37 C.F.R. §41.37(c)(ii).

EXHIBIT A

cientifica

Nanocrystalline Materials

Technology White Papers
nr. 4



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NANOCRYSTALLINE MATERIALS

Technology White Papers nr. 4

Release Date: October 2003

Published by Científica

Científica, Ltd.
www.cientifica.com

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Origin of content

The free reports in this series are extracted from the technology reports that make up the Nanotechnology Opportunity Report collection and are designed to offer an introduction to the variety of technologies that fall under the nanotechnology umbrella. The full reports also include 'opportunities' sections, covering the various applications of the technology and their effects on markets, and a list describing the companies involved in the technology.

Introduction

This report covers bulk nanocrystalline materials and coatings. Metals and ceramics (these being metal oxides in the context of this report), both bulk and in coatings, make up most of the content of the report. Both these materials are generally made up of crystals the size of which are measured in micrometers. Reducing the size of the crystals can have quite dramatic effects on the properties of the bulk material, particularly increasing strength.

The creation of nanocrystalline materials is in its infancy. A few companies are starting to commercialize products and significant growth can be expected, penetrating the huge markets for structural materials and coatings. The new products will not be without competition from other materials, especially nanocomposites, but there are markets where these new materials will be the favored choice in the future.

Nanocrystalline materials

Nanostructure and properties

Bulk metals and ceramics and coatings

Metals and ceramics are generally polycrystalline, meaning that they consist of many randomly oriented crystalline regions, or grains. Reducing the size of the grains (also referred to as crystals or domains) in existing materials can have a big impact on bulk material properties. As the grain size in a metal, for example, moves into the nanoscale, an increasing proportion of the atoms in the solid are found on grain boundaries, where they behave differently from those not on boundaries. Their behavior starts to dominate the behavior of the material (at roughly 5 nm, 50% of the volume will be grain boundaries).

Note that a nanocrystalline material need not just be a bulk solid or surface but can be a powder, or nanopowder, thus there is overlap of the use of the terms nanocrystal and nanoparticle for some materials. In general, though, the important properties of nanocrystalline nanoparticles stem from their nanoparticulate nature and will not be considered here (this applies, for example, to nanocrystalline semiconductor quantum dots, where size is the critical property). This report will focus largely on bulk nanocrystalline materials. Nanopowders can, however, be the source material for making nanocrystalline solids and coatings.

It is often stated that as grain sizes move into the nanoscale, metals get stronger and harder (and more brittle) while ceramics become more ductile (malleable). This is an approximation, though, and in fact the reality is more complex and dependent on what part of the nanoscale the grain sizes are in. The approximation stated works, for example, in metals with grain sizes down to about 10 nm, below which a decrease in hardness and strength is seen. In ductile nanocrystalline ceramics, grain sizes are often below this size. The traditional theory behind the change in hardness with grain size is the Hall-Petch relation, which states that hardness increase is inversely proportional to the square root of the grain size (the basis of the effect, put simply, is the limiting of the spread of dislocations, or breaks in the crystal structure, by an increasing number of grain boundaries). This makes for dramatic increases in hardness when going from normal grain sizes to around 10-20 nm.

(Note that grain size is not the only way in which the spread of dislocations can be controlled—creating layered materials can achieve the same effect.)

Other properties of nanocrystalline metals, apart from increased strength and hardness, include higher electrical resistance, increased specific heat capacity, improved thermal expansion properties, lower thermal conductivity and improved magnetic properties.

In ceramics, the increase in ductility when they become nanocrystalline is accompanied by improved toughness (the ability to withstand an impact or applied strain), or reduced brittleness, and improved ability to bond to a metal component. The toughness leads to increased wear resistance (2-4 times that of a traditional ceramic coating) but, somewhat counter-intuitively, grinding and polishing, which is often performed after laying down a ceramic coating, is actually easier with nanocrystalline ceramics.

Increased ductility is especially valuable in ceramics, where brittleness is often a major problem, and superplasticity has been observed in both nanocrystalline metals and ceramics at around 200°C, making for easier forming of materials. The most important impact of increased ductility in ceramics is on ceramic coatings for machinery that resist wear and corrosion. These materials generally fail not because of wear but because of insufficient toughness.

Research into new nanocrystalline ceramic coatings holds promise, with materials such as tungsten-carbide cobalt, chrome oxide and yttria stabilized zirconia being investigated.

The ductility of nanocrystalline ceramics also creates the possibility of drawing them into wires, offering applications based on the superconducting properties of some ceramics.

In metals it is the improved strength that is most sought after, and the increased stiffness can actually be a problem, since ductility is useful not just in manufacturing but also in terms of behavior on impact, an important consideration in cars, for example.

To give an idea of the changes that can be achieved in metals, Rensellaer Polytechnic researchers measured the strength of nanocrystalline copper and found it to be 5 times harder than conventional copper. In fact today's strongest steels have about 10% of the theoretically possible maximum strength.

Loss of ductility in nanocrystalline metals can actually be avoided. This can be achieved by creating a mixture of nanoscale and microscale grain structures. Late in 2002, researchers at Johns Hopkins University managed to create copper that was 75% nanocrystalline with 25% of microcrystalline grains dispersed in the material. It proved to be 5-6 times the strength of normal copper but without any loss in ductility. A ceramic structure with microscale grains embedded in a predominantly nanocrystalline matrix has also been found, by the US's Office of Naval research, to produce the best properties for their aluminum and titanium oxide ceramic coatings.

Note that there are competing approaches to making stronger steels while retaining ductility. Traditional steel has carbon particle inclusions; in 2001, a group at NKK in Japan demonstrated a way of including nanoparticles in the rolling process for steel to make these inclusions smaller, resulting in a new steel that is significantly stronger than existing varieties but with the formability required for uses in creating car engine parts or body components. Toyota, which was involved in the project, is already using the new steel.

Alternatively, crystalline structure can be avoided altogether, by creating amorphous metals, in which there is no particular pattern in the atomic order (glass is a classic example of an amorphous material). In 2001, the US Department of Energy's Idaho National Engineering and Environmental Laboratory developed a spray-on super-hard (and corrosion-resistant) steel amorphous coating that proved remarkably resilient, approaching the best tungsten-carbide coatings in hardness (the application of heat can convert this amorphous coating into a nanocrystalline form), with both strength and hardness reaching 45% of the theoretical maximum. While only coatings have been achieved so far, the hope is to be able to build thick industrial steel sheets out of this material.

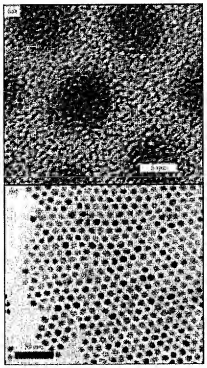
Chemical reactions and catalysis

Increased reactivity is also seen in bulk nanocrystalline materials because of increased surface area. This can be useful with respect to direct chemical reactions or in terms of catalytic activity. An example is the lithium tin nanocrystalline alloy made at Brookhaven National Labs early in 2002, in which the 20-30 nm grain size gave improved reactivity, and potentially a more powerful battery. Also, back in 1999, researchers at MIT started creating nanocrystalline high temperature catalysts (used, for example, in the catalytic combustion of natural gas—an area of great interest at the moment) that could be created at lower temperatures than were normally required but would still withstand the high operational temperatures.

Nanostructured cerium ceramics have been shown to offer catalytic activation for sulfur dioxide reduction and carbon monoxide oxidation at significantly lower

temperatures than traditional versions of these catalysts, and they have also shown greater resistance to poisoning (the loss of catalytic reactivity caused by contaminants). Some materials only develop catalytic activity once they become nanostructured, an example being cadmium selenide, which is not normally photocatalytic but becomes so when nanocrystalline, and offers the ability to 'fix' (a term taken from photosynthesis) waste carbon dioxide.

Other nanocrystalline materials of note



TEM image of (hcp) Co nanocrystals (NCs). Colloidal synthetic methods allow Co NCs to be produced in several distinct crystal polymorphs with varying degrees of crystal perfection. Courtesy of IBM.

Nanocrystalline and nanoporous silicon showed promise in a few research results in 2001 because of their ability to emit light. Nanocrystalline silicon has properties, in addition to electroluminescence (of interest for semiconductor laser applications), such as photoluminescence, thermally-induced acoustic emission, and refractive index changes that can be controlled. The attraction here is the compatibility with silicon-based electronics. Not much research of note has been seen in this area in 2002, however.

Towards the end of 2002, though, nanocrystalline nanoporous silicon was shown to have a property applicable to a very large and dynamic market, that of flat panel displays. Researchers at Tokyo University created nanocrystalline silicon film with a pore structure that varied with depth and in which the electrons could be accelerated to the surface, creating what the researchers called a 'vacuum-less cathode-ray tube'.

Nanocrystalline diamond is another interesting material. Argonne National Laboratory created a film of diamonds that are only 3-5 nm across (each containing around 1000 atoms) by using buckyballs (molecular cages of 60 carbon atoms) as a feedstock. The tiny size changed the electrical properties of the diamond film, when compared with normal diamond films, because of electron transport at grain boundaries (aided by nitrogen), meaning that the diamond can be made to behave as a semiconductor (researchers at CSEM in Switzerland have achieved similar results). The advantage of diamond over silicon is its ability to tolerate extreme environments. It also exhibits much less friction than silicon, and is much stronger, which may be useful in microelectromechanical systems.

The relationship between nanocrystals and magnetism holds the possibility of making stronger permanent magnets. Grain size is already a factor in magnetic materials that

is controlled to achieve desired properties, especially the smallest possible magnetic domains in recording media. Below a certain size a grain is liable to spontaneously switch its magnetic orientation (this relates to the superparamagnetic limit). The latest materials for recording media have elongated grains that allow the total volume of a grain to remain above the limit while presenting a smaller surface profile. Theoretical limits are being approached in this area but in permanent magnets there is still a lot of scope, with some suggesting that 4-5 times the strength of current permanent magnets could be achieved if the ideal grain structure could be attained.

Finally, it should not be forgotten that nature is a master of nanomaterials and nanocrystalline materials are no exception. Many groups are working on borrowing from nature to make nanostructured materials, either by emulating natural processes or by modifying biomaterials directly (for example, by taking the shells of tiny marine organisms, called diatoms, and chemically modifying them). However, natural materials like this are not generally nanocrystalline in the sense of having multiple nanoscale crystal domains, but tend to be instead a more globally structured crystalline form. An example of some work done in this area, which does indeed produce a nanocrystalline material as an approximation of the material that nature produces, is research done on hydroxyapatite by MIT.

Hydroxyapatite is the main mineral component of bone and synthetic versions tend not to be anywhere near as strong as natural ones. MIT's version was built by coalescing nanoscale particles into a solid that was much closer to the strength of bone than traditional synthetic versions.

Production techniques

Materials can be made nanocrystalline using quite a wide variety of techniques.

For coatings, new techniques, such as pulsed laser deposition or electrodeposition, or variants of chemical vapor deposition techniques, have been developed that can coat a surface with nanocrystalline metals, semiconductors and other materials.

Thermal spraying is an increasingly popular way of converting the new generation of nanopowders into nanocrystalline coatings—heat is used to partially melt the powders so that they fuse when they form the coating. Varying the amount of melting can lead to different structures. A variation of this technique, using a plasma (a hot, ionized gas) into which nanoparticle agglomerates are fed, is used to produce the ceramic coating used by the US Navy (previously mentioned) and other ceramic coatings. The nanostructure is created by retaining some of the original nanoparticle structures (thus only limited melting can be allowed), or by mixing nanoparticles with different melting temperatures, or by allowing the nanostructure to form in the applied coat through the combining of non-miscible materials. This approach was used to achieve the useful mixture of nanoscale and microscale grains.

Electrodeposition is an old coating process but has been successfully customized to produce coatings with grain sizes down to 5 nm. It is a commercially attractive

process because it can be carried out at room temperature and can be used for large-scale production.

To create bulk materials that are nanostructured in three dimensions, powder compaction, crystallization of initially amorphous material, and severe plastic deformation processing are the leading methods but approaches such as electrodeposition have also been used.

Powder compaction methods involve first producing nanoscale particles which are subsequently fused together using combinations of pressure and heat. Nanoparticles can be made to partially melt and fuse at temperatures below the normal melting point of a material. These methods have been limited by the challenge of controlling contamination or oxidation of the high surface area particles that are the raw material, and the resulting materials also tend to be porous, but the methods offer the advantage of being able to combine different particles to create nanocomposites.

Severe plastic deformation (SPD) processing techniques are applicable mainly to metals. These methods all take advantage of the ability of the crystals within metals to subdivide into domains as small as 20 nanometers when they are subjected to large shearing strains while under high pressure, though crystal sizes a little below 100 nm are more common. The strain can be applied in a number of ways, such as extrusion, bending or twisting, or rolling.

SPD approaches have the advantage over powder methods for bulk solids that they can create nanocrystalline materials with minimal porosity and contamination.

SPD is scalable and is thus being pursued for commercialization. However, there is an inevitable additional cost and sometimes the resulting material contains unwanted stresses.

The super-strong but ductile copper made at Johns Hopkins University used a variant of deformation processes. Rolling created the nanostructure and subsequent annealing (a process involving heating to below the melting temperature, usually used to relieve stresses) led to the formation of some micrometer-sized grains.

Purdue University researchers made a serendipitous discovery in mid 2002 that seems obvious in retrospect. Shavings from working metals are, of course, subjected to great stress. The Purdue researchers discovered that the materials are often nanocrystalline as a result, offering the possibility of making nanocrystalline bulk materials out of waste that would normally be melted down and recycled.

Crystallization of amorphous materials can produce the finest scale nanostructures, but is limited to materials that can be first put into an amorphous state. However, approaches such as sol gel allow the creation of a wide variety of materials with a very well-controlled nanostructure (if not necessarily nanocrystalline) and have been used to make ultra-non-stick ceramic coatings.

The lithium tin nanocrystalline alloy made at Brookhaven National Labs, which was used as a high-performance electrode, was created using a rather original technique, reacting lithium hydride with tin oxide, but with more of the former than was needed to react fully. This produced a lithium tin alloy with lithium oxide left over. Repeatedly adding and removing hydrogen produced a nanocomposite with grain sizes of 20-30 nm. The researchers say that other elements that form stable metal hydrides could be used to make nanocomposite materials with this method, with potential applications not just in batteries but also in catalysis.

EXHIBIT B

Min Invas Ther & Allied Technol 2000: 9(1) 107–118

Optimisation of processing and properties of medical grade Nitinol wire

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Summary

The purpose of this paper is to review the current processing and resultant properties of standard Nitinol wire for guide-wire applications. Optimised Ti-50.8at%Ni wire was manufactured according to industry standards by precise control of the composition, cold work and continuous strain-age annealing. Mechanical properties of this wire are reported from −100°C to 200°C to demonstrate the effects of test temperature. Within the 'superelastic window' the plateau stresses are linearly related to test temperature. Additional ageing treatments can be used as a tool to fine-tune transformation temperatures and mechanical properties. A review of the fatigue properties of thermomechanically-treated Nitinol wire shows that they are affected by test temperature, stress and strain.

Keywords

Nitinol, shape-memory, superelasticity, mechanical properties, ageing, fatigue

Introduction

The growth in the use of Nitinol in the medical industries has exploded over the past 10 years. Patients and care-providers have encouraged the transition from traditional open-surgical procedures that require long hospital stays, to less-invasive techniques, which are often performed in out-patient facilities [1]. This demand for minimally-invasive procedures has required novel instrumentation and implants to be designed by engineers and physicians. An increasing number of these devices use Nitinol as the critical component. Examples of these medical applications are richly illustrated in companion articles in this journal [2,3], and range from endoscopic instruments to implants, such as stents and filters. It is interesting that the majority of these devices depend on mechanical superelastic behaviour, which is a significant departure from the original thermal shape-memory industrial uses of Nitinol.

Since the 'discovery' of the shape-memory effect in TiNi alloys in the 1960s, metallurgists have investigated methods to control transformation temperatures and mechanical properties through alloying additions, improved melting practices and thermomechanical processing (see, for example, References 4 and 5). The production of many thousands of kilometers of wire for such diverse products as cellular telephone antennae, eyeglass frame components, guidewires, undergarment supports and orthodontic archwires profoundly influenced the acceptance of Nitinol in the marketplace. These commercial opportunities have allowed Nitinol suppliers to focus on improving

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processes for a few standard alloys, rather than pursuing a myriad of 'boutique alloys' with niche applications. The composition and processes have been refined so that, for example, the transformation temperature in final products is routinely controlled to within ± 3°C. More recently, the availability of seamless tubing and sheet have provided designers with additional tools to solve engineering problems. Furthermore, microfabrication techniques, such as laser machining [6] and photoetching [7], have also contributed to the increase in the number of miniature devices made from Nitinol.

Accordingly, Nitinol properties have become very predictable, which is a basic requirement of design engineers. As the Nitinol industry has matured over the past two decades, terms such as 'shape-memory', 'superelasticity', 'recovery forces', 'plateau stresses', and 'transformation temperatures' are now recognised by more than just a select few metallurgical specialists. Although design engineers have a good understanding of the basic properties of the alloys, they still have many good questions. Typically these include:

- Are the mechanical properties constant over a wide range of temperatures?
- Can we adjust the transformation temperature without modifying the mechanical properties?
- Do the shape-memory and superelastic properties imply that Nitinol has an infinite fatigue life?

The purpose of this article is to address these questions by reviewing the processing and resultant properties of Ti-50.8at%Ni wire that has been manufactured for medical guide-wire applications. Furthermore, this article will focus on the effects of standard continuous thermomechanical processes, rather than long-term 'batch' processing, which was more common in the 1970s and 80s.

Processing

Optimisation of the superelastic properties of Nitinol for a specific product is achieved through a combination of cold work and heat treatment. The first step in optimising the thermomechanical treatments of wire and tubing products is to draw the material through a series of dies, to achieve 30–50% reduction in cross-sectional area [8]. Past methods have employed a long-term batch annealing process but, to attain a more uniform product, continuous strand strain annealing is the most effective method. With this method, the Nitinol wire is under constant strain during the annealing process. Continuous 'strain annealing' ensures that the entire spool will be processed with the identical thermomechanical treatment, resulting in a product with uniform properties from end to end.

Figure 1 shows a typical continuous-strand strain straightening process line.

Continuous-strand straightening usually occurs in a temperature range of 450–550°C under a stress of 35–100 MPa. As the wire moves into the heat zone it will initially want to shrink in length and grow in diameter, due to the shape-memory effect not suppressed by the cold work of the drawing process (springback). The wire temperature quickly increases, its strength will drop and the applied strain will straighten the wire and, depending on the strain, reduce the wire diameter slightly. In the continuous process it is difficult to measure the active strains during straightening as they occur inside the furnace. However, the following vertical straightening example can help define the strains operating during the continuous process.

During vertical straightening of discrete lengths of wire, the wire is heated via electrical resistance and is therefore exposed to make visible measurements. As a 1.5 mm diameter wire was being electrically straightened, it showed a maximum springback of 1.2% during heating and a 2.4% extension strain at the end of the straightening cycle. Similar strains would be expected with the continuous-strain straightening method.

Straightness, mechanical properties and the active A_f are all affected by the speed and temperature parameters of the straightening process. As with all thermally-activated processes, time at temperature controls the final properties of the wire. More time at temperature softens the wire and moves its mechanical properties toward a fully annealed product, while short times leave the material closer to the high strength cold-worked state. To optimise the superelastic properties, a balance must be developed between these two extremes. The requirements of

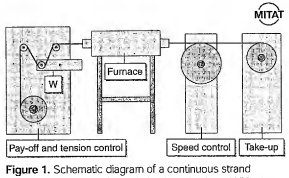

Figure 1. Schematic diagram of a continuous strand annealing equipment for optimised production of Nitinol superelastic wire.

the final product will help define the process parameters. A high torqueable guide-wire may require slower speeds than a high strength wire that has a table-roll straightness requirement. Additional speed and temperature adjustments may be necessary to meet any active A_f requirements (see discussion below) as well.

Properties

In this section we will consider the methods of characterising the thermal and mechanical properties of thermomechanically-processed wire. The focus will be on products that are superelastic between room temperature and body temperature. We will document the mechanical properties from −100°C to 200°C, to illustrate how test temperature affects performance. Furthermore, since many wire and tubing products are given additional thermal shape-setting, we will establish the effects of ageing time and temperature treatments on transformation and mechanical properties. Finally, since many Nitinol medical devices are used in (human) fatigue environments, we will discuss the influence of strain amplitude and test temperature on bending fatigue behaviour.

Transformation temperatures

Harrison [9] cataloged >20 techniques that have been used to measure the changes associated with the shape-memory transformation. Two of the most fundamental ways to determine the **qualitative** transformation temperature involve sound and feel. Even a novice can distinguish between the 'ping' from austenite and 'thud' from martensite when dropped on the floor. Although this is not a highly quantitative means to measure transformation temperatures, it has been used to sort alloys quickly without sophisticated equipment. Another qualitative method is to feel the alloy. Martensite 'feels' rubbery when bent, whereas austenite feels 'springy'.

These two simple examples cited above illustrate that the martensitic transformation affects a variety of properties. However, Harrison [9] offered the sage advice that the chosen measurement technique should parallel the actual function of the product. For example, many medical customers request certification of the A_f temperature to ensure that the product is austenitic above a certain application temperature. These customers generally specify that the measurements are obtained by either differential scanning calorimetry (DSC) or free recovery ('active') techniques. DSC measures the heat released and absorbed during the martensitic (exothermic) and austenitic (endothermic) transformations, respectively [10, 11]. Free recovery, however, is by far the most simple and often the most useful method to measure A_f. This technique only requires the following steps, which simulate a shape-memory cycle:

- cool to a low temperature (for example in a cooled alcohol bath);
- bend the sample to a prescribed strain (2–3%);
- watch and record the temperature at which the sample returns to its original shape when heated: this is defined as the A_f temperature.

Free recovery can also be instrumented in order to obtain a permanent record of the results [12, 13]. Both of the above techniques have the benefit that they are straightforward to conduct, amenable to use for small specimens, require minimal sample preparation (especially free recovery) and are reproducible.

Figure 2 compares the DSC thermogram and instrumented free-recovery measurements from the same wire. The DSC records the heat flow during both cooling and heating, whereas free recovery records the deflection recovery only during heating. The key transformation temperatures, martensite start (M_s), martensite finish (M_f), austenite start (A_s) and austenite finish (A_f), are marked as appropriate on both charts. Also included are atomic models of the austenite (cubic structure) and martensite (monoclinic structure) to help the reader visualise the transformations.

Note that the DSC graph shows an R-phase peak during cooling from a high temperature. Although an in-depth discussion of the R-phase is beyond the scope of this paper, it is important to point out that the R-phase is another shear transition in competition

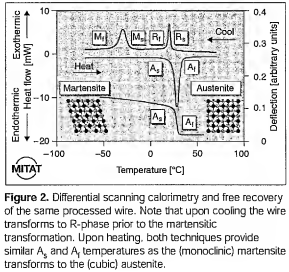

Figure 2. Differential scanning calorimetry and free recovery of the same processed wire. Note that upon cooling the wire transforms to R-phase prior to the martensitic transformation. Upon heating, both techniques provide similar A_s and A_f temperatures as the (monoclinic) martensite transforms to the (cubic) austenite.

with martensite [14]. In the case shown in Figure 2, the R-phase forms around room temperature. With further cooling, the martensite transformation begins at about −23°C (M_s) and is fully martensitic below −38°C (M_f). When the sample is reheated, the reverse transformation begins at about 22°C (A_s) and finishes at an A_f of 32°C. Note that there is a wide hysteresis between the M_f and A_f, which is characteristic of shape-memory alloys. The origin of the hysteresis is attributed to microscopic internal friction effects [15]. The A_s (24°C) and A_f (32°C) data from the free recovery method are nearly identical to those from DSC.

Mechanical properties

Based on the transformation behaviour shown in Figure 2, the wire should be fully austenitic above 32°C. However, an important characteristic of shape-memory alloys is that stress can trigger the martensitic transformation at temperatures above A_f (the 'thermoelastic' effect [15]). From a thermodynamic viewpoint, this means that it is easier (lower free energy) for the wire to create martensite in response to the applied stress than to deform plastically (dislocation formation) [15,16]. Stress-induced martensitic transformations can be easily understood by considering Figure 3 [17]. This diagram compares atomic motions in response to an applied stress by traditional Hookian elastic (top) and transformational superelastic (bottom). For Hookian elasticity, which represents conventional materials, such as stainless steel, the atomic bonds 'stretch' up to about 0.5% before plasticity occurs. In contrast, the austenitic structure depicted on the bottom left structure transforms into martensite with applied stress. As the magnitude of the stress increases from left to right, the amount of martensite increases. Up to 10% strain can be accommodated by stress-induced martensitic transformations. The martensitic structure formed by superelasticity is identical to that formed through the shape-memory process, as illustrated in Figure 2.

Figure 4 is a schematic stress–strain curve that corresponds to this model of transformational superelasticity. When the wire is pulled beyond its Hookian elastic limit (approximately 1.5% strain in Nitinol), there is an apparent 'yield' at a critical stress. Atomistically, this is represented by the onset of martensitic transformation, as shown in the second diagram in Figure 3. The wire can be further stretched at a relatively constant stress along the 'loading plateau' until the entire structure has transformed into martensite. As the stress is removed, the martensite immediately recovers elastically (linear unloading) and then begins to revert back to austenite on the 'unloading plateau'. The ability of the material to return to its original shape when the stress is released is an important attribute for many products,

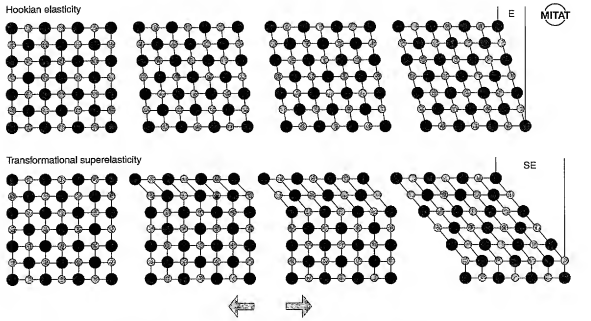

Figure 3. Schematic representation of the atomic motions associated with Hookian elasticity observed in conventional materials and transformational superelasticity of Nitinol. (From Stöckel and Yu, Ref. 17.)

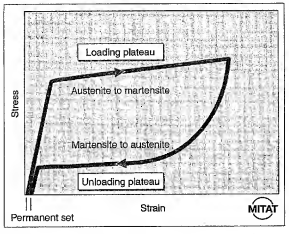

Figure 4. Schematic stress–strain curve of superelastic Nitinol. There is a transformation from austenite to martensite that begins at the apparent yield stress. The plateau stress remains nearly constant with increasing strain as the amount of martensite increases. Upon unloading, the martensite reverts to austenite along the unloading plateau. The 'permanent set' measures any residual strain.

such as guide-wires, to minimise kinking. Any residual strain is caused by an accumulation of plastic strain and is measured by the 'permanent set', as shown on the figure. Note that the stress–strain curve exhibits a stress hysteresis that, similar to the thermal hysteresis discussed above, is due to microstructural frictional effects. The magnitude of the stress hysteresis plays an important role in the design of many Nitinol applications, such as Nitinol eyeglass frames. A high loading stress is required to resist easy bending of the frame, whereas the unloading stress should be low so that the temples exert a gentle pressure against the head. Stöckel [2] discusses other examples of this 'biased stiffness' property.

Effects of test temperature

The tensile curves shown in Figure 5 illustrate that the mechanical behaviour of Nitinol varies greatly from −100°C to 150°C. In these tests, wires with an A_s of −22°C and A_f of 11°C were pulled to 6% strain, unloaded to zero stress and were then pulled to failure. At the lowest test temperatures, the wires are martensitic and the high residual strains are fully recovered by heating above A_f (the shape-memory effect). From about 0°C to 100°C the tensile curves exhibit superelastic 'flags', and we note that it becomes more difficult to stress-induce martensite as the test temperature increases. Along with the increase in the plateau stresses, the permanent set also increases with temperature. The tensile behaviour at 100°C, with a high permanent set, but a well-defined unloading curve, indicates that deformation is accommodated by a combination of stress-induced martensite and conventional plasticity. Above 150°C, however, the wire deforms by plastic mechanisms rather than martensitic transformations, which results in a linear unloading curve. The temperature where it is too difficult to stress-induce martensite is defined as M_d; in the present case, M_d is between 100°C and 150°C.

The effects of test temperature on the tensile curves shown in Figure 5 may be further analysed by considering each of the key attributes. For example, Figure 6 shows the temperature dependence of the permanent set from these wires after unloading from 6% strain. At lower temperatures, the unresolved strain is due to deformation of the martensite, and can be recovered by heating above A_f. The residual strain is nearly zero between 0°C and 60°C, which defines the superelastic 'window' for this alloy. As noted above, the non-recoverable plastic strain is about 1 % at 100°C and then increases to about 3 % at 150°C. Many medical applications require superelastic behaviour between room temperature and body temperature. Therefore, this 60°C window is perfectly centered about the intended application range.

Figure 7 shows the effects of test temperature on the loading, unloading and ultimate tensile stress. We see that there is a linear relationship between plateau stress and temperature between about 0°C and 60°C for the unloading plateau and up to 150°C for the loading plateau. These variations in plateau stress follow the Clausius–Clapeyron relationship for a first-order transformation [16]:

$$\frac{d\sigma}{dT} = \frac{-\Delta H}{T\varepsilon_0}$$

Where $d\sigma$ is the change in plateau stress, T is the test temperature, ΔH is the latent heat of transformation (obtained from DSC measurements), and ε_0 is the transformational strain. ΔH and ε_0 are controlled by the crystallography of the transformation and can be considered constants. The right side of the equation therefore defines the 'stress rate' for the stress-induced transformations. For the present case, the stress rate is 6.1 $MPa°C^{-1}$, which is within the typical range of 3–20 $MPa°C^{-1}$ for Nitinol alloys [18]. The consequence of this relationship is that the mechanical properties of Ti–Ni alloys depend directly on the transformation temperature and test temperature.

The ultimate tensile stress (UTS) gradually decreases from approximately −100°C to 150°C, with a slight minimum at 150°C. The UTS and plateau

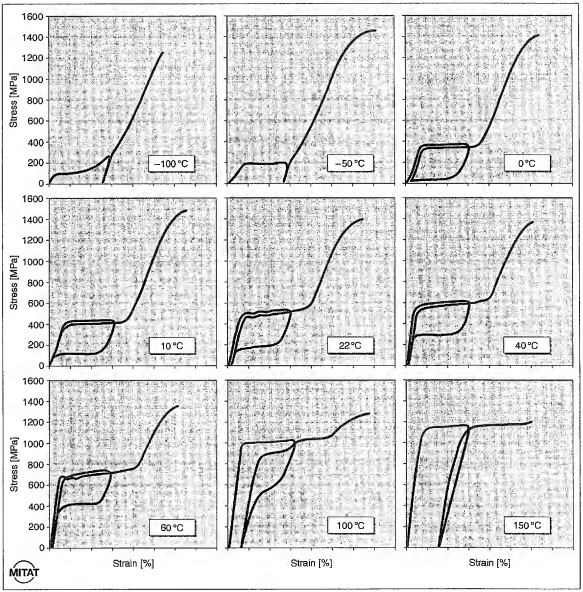

Figure 5. Effect of test temperature on the mechanical behaviour of Nitinol wire. Note that there is a systematic increase in the loading and unloading plateau stresses with increasing test temperature. Below 0°C, the structure is martensite and, above 150°C, the graph shows conventional deformation of the austenite. The intermediate temperatures all show classic transformational superelasticity.

stress converge above this temperature, which is a further indication that M_d is near this temperature. In Figure 8, we see that the elongation is fairly constant up to about 150°C and then drops at the higher temperatures. The combination of the low ductility and high stresses above 150°C may indicate a toughness minimum for this material.

Effects of ageing heat treatments

Several investigators have shown that optimal superelastic performance can be achieved in Nitinol alloys that have a combination of cold work and ageing heat treatments [18, 19]. Precise control of these thermomechanical treatments can lead to reproducible mechanical properties and transformation temperatures. TiNi alloys with 50.8% Ni respond well to ageing heat treatments to 'tune in' the

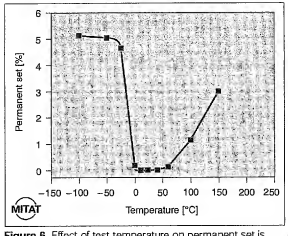

Figure 6. Effect of test temperature on permanent set is shown from the data in Figure 5. The 'superelastic window' extends from approximately 0°C to 60°C, where there is minimal residual strain after unloading from 6 % strain. Below 0°C, the strain can be recovered by heating above A_f – 11°C (the shape memory effect) and at higher temperatures the residual strain is due to plasticity.

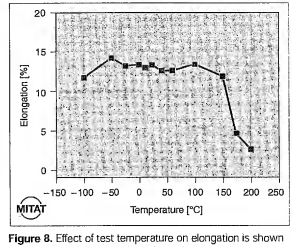

Figure 8. Effect of test temperature on elongation is shown from the data in Figure 5. The elongation does not vary much with temperature up to approximately 150°C. The drop in ductility at the high temperatures may signify a toughness minimum.

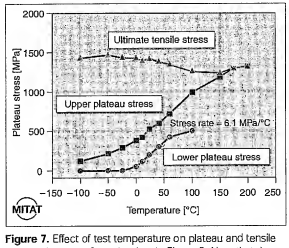

Figure 7. Effect of test temperature on plateau and tensile stresses is shown from the data in Figure 5. Note that there is a linear relationship between plateau stress and test temperature from about 0°C to 100°C with a slope, or stress rate of 6.1 MPa/°C^{-1}. The ultimate tensile stress shows a gradual decrease with increasing temperature with a minimum at the M_d of 150°C.

desired properties. Nishida *et al.* [20] established the effects of ageing time and temperature on the Ti-Ni precipitation reactions in Ti-51%Ni alloys by metallographic methods. They observed precipitation sequence of $Ti_{11}Ni_{14}$ – Ti_2Ni_3 – $TiNi_3$ in the TiNi matrix at temperatures between 500°C and 800°C and for times up to 10 000 h and presented the data in a time–temperature–transformation (TTT) diagram. Their work gave great insight into the metallurgical tool of controlling precipitation reactions in Nitinol alloys.

Clearly, however, the times investigated by Nishida *et al.* [20] are significantly longer than can be tolerated in a production environment. Therefore, straight wires from the previous section were aged between 300°C and 550°C for 2 – 180 min, to characterise the effects on transformation temperature and mechanical properties. Figure 9 illustrates these effects on the A_f temperature. We note that the transformation temperature does not change significantly at 300°C. Also, at 500°C, the A_f increases slightly at short times, but does not increase rapidly. The intermediate temperatures, namely 350 – 450°C, have a greater impact on the transformation temperature. At the highest ageing temperature, 550°C, there is an initial decrease in A_f and then a rapid increase. Admittedly, these trends of temperature and time on the A_f may appear counter-intuitive. However, more clarity is gained by grouping the time–temperature conditions to obtain common A_f temperatures. Figure 10 is such a TTT diagram, where each 'c-curve' represents the loci of constant A_f. This figure illustrates that there is a maximum in the precipitation reaction at about 425°C; i.e., the A_f increases most rapidly after heat treatments at 425°C. For example, the A_f increases from 11°C in the as-straightened wire, to 30°C after ageing for only 10 min. To reach the same 30°C A_f at 500°C takes about 60 min and at 300°C the time exceeds 180 min.

It is certainly beyond the scope of this article to review the metallurgy of precipitation reactions. However, the shape of these curves can be understood

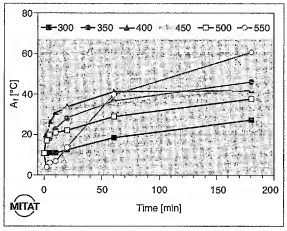

Figure 9. Effect of ageing temperature and time on the transformation temperature of Ti-50.8% Nitinol wire with a starting A_f temperature of 11°C are shown. Note that all of the ageing temperatures tend to increase the transformation temperature, although at 550°C there is an initial decrease.

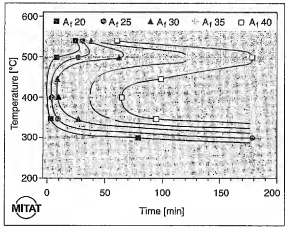

Figure 10. Effect of ageing temperature and time on the transformation temperature of Ti-50.8% Nitinol wire with a starting A_f temperature of 11°C are shown. The data from Figure 9 are re-plotted to illustrate the conventional time–temperature–transformation (TTT) diagram. Note that the maximum precipitation rate is about 400°C. Between 500°C and 550°C the precipitates dissolve and tend to lower the A_f. A new precipitate forms at 550°C (see text for more details).

by briefly exploring two factors that govern diffusional nucleation and growth of precipitates [21]. At high temperatures, there is sufficient thermal energy to permit rapid diffusion of Ni and Ti atoms in the matrix. However, it becomes more difficult for the atoms to form a precipitate nucleus as the temperature increases. At lower temperatures, however, just the opposite situation occurs: here we have high nucleation rates, but low diffusion rates. These two processes are optimised at the intermediate temperatures (350 – 450°C) to achieve maximum precipitation rates. The A_f change, therefore, is due to relative Ni and Ti atom diffusion, where the Ni atoms congregate in the precipitates and the Ti atoms move to the TiNi matrix phase. As the matrix becomes enriched in Ti, the transformation temperature increases, as expected from the relationship of composition to transformation temperature [22]. Although the overall composition of the material remains Ti–50.8% Ni, localised shifts of composition can affect the transformation temperatures.

The trends in the TTT curves indicate that a single precipitation reaction ($Ti_{11}Ni_{14}$) occurs in the temperature range 300–500°C. Between 500°C and 550°C, however, there are 'cusps' in the A_f curves. Above 500°C, the $Ti_{11}Ni_{14}$ precipitates dissolve and there is a corresponding **decrease** in the transformation temperature, as the Ni atoms diffuse back into the matrix. At 550°C the Ti_2Ni_3 phase precipitates require an even greater amount of Ni to diffuse away from the matrix. Precipitation of this phase, therefore, will again increase the A_f, but at a different reaction rate than for $Ti_{11}Ni_{14}$. These findings are consistent with Miyazaki's microstructural study of Ti-50.6%Ni alloys after ageing for 60 min at 400°C, 500°C and 600°C [19]. His results demonstrate that the maximum density of $Ti_{11}Ni_{14}$ precipitates is obtained at 400°C.

The effects of the ageing treatments on the loading plateau stress are shown in Figure 11. Since the wire was 'strain-aged' during the initial processing, these additional ageing treatments do not increase the loading plateau. Ageing temperatures in the 300–500°C range systematically decrease the loading plateau, as we would expect with the increase in A_f temperature. At 550°C, there is an initial decrease in loading plateau stress and then a more rapid decrease as ageing and annealing processes occur. The effects of ageing on the UTS are more interesting, as seen in Figure 12. Here the ageing treatments between 300°C and 450°C increase the UTS. This illustrates that the $Ti_{11}Ni_{14}$ precipitates are effective barriers to dislocation motion. Although we know that precipitates form during ageing at 500°C and 550°C, there is a dramatic decrease in UTS, especially at 550°C. The decrease in plateau and tensile stress at 500°C and 550°C illustrates that this is an effective temperature range for annealing (dislocation annihilation).

The above ageing discussion points out that the transformation temperature can be readily adjusted by

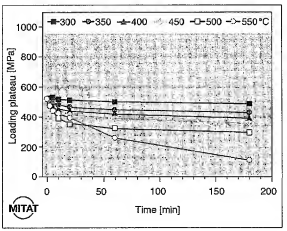

Figure 11. The effect of time and temperature on the loading plateau of aged Ti-50.8% Nitinol alloy. These stress data correspond to the A_f temperatures shown in Figures 9 and 10. There is a systematic decrease in plateau stress with increasing temperature. There is a more dramatic effect at 550°C.

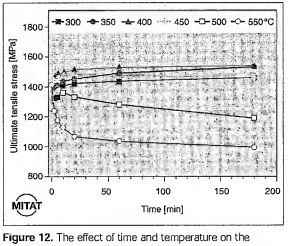

Figure 12. The effect of time and temperature on the ultimate tensile stress. Ageing temperatures between 350°C and 450°C tend to increase the tensile strength due to precipitation hardening. At 500°C and 550°C, the annealing effects dominate and lower the strength.

selecting an appropriate time and temperature. Higher A_f temperatures are achieved by ageing in the 300 – 500°C range. Additionally, the A_f can be lowered by short ageing times between 500 and 550°C.

Fatigue properties

Fatigue life is a major concern for biomedical implant applications. For example, the US FDA requires proof of fatigue resistance of 10 years (400 million cycles) in simulated body environment for intravascular stents [23]. Pedersen *et al.* [24] measured 6% average diametral strain in proximal aorta at 100 mmHg pressure differential. Therefore, an implanted device could be exposed to pulsatile strains as high as 6%. The actual mean strain that the implant is subjected to depends on material and design factors. However, whether the stent is manufactured using woven wire, etched sheet, or laser-cut tubing, the strut sections undergo cyclic bending deformation. Although several papers have reported on the fatigue properties of Ti–Ni alloy plates and bars [25] under tension–compression conditions, only a few recent papers have been published on the fatigue life of Ti–Ni wires [26, 27]. Furthermore, many Nitinol products are tested under accelerated pulsatile conditions that allow only periodic observations to ensure that the devices have not fractured (for example, see Reference 28). A logical approach, however may be to supplement these 'submission tests' with more fundamental bend–fatigue studies on wires or stent elements to aid in the design phase. The purpose of the present section, therefore, is to review the effects of strain amplitude, stress and test temperature on the fatigue life of binary Ti–Ni alloy wires.

Miyazaki *et al.* tested cold-worked and aged Ti-50.0at%Ni [27] and Ti-50.9at%Ni [28] wires in a rotary-bend apparatus. The specimens were fixed in a bent shape with a suitable radius of curvature to induce a desired strain at the specimen surface at specified temperatures above and below A_f. Figure 13 shows the (outer fibre) strain amplitude (ε_a) versus number of rotations to fracture (N_f) relationship at each test temperature for the two alloys. The upper diagram shows three curves for the Ti-50.9at%Ni alloy and the data for the Ti-50.0at%Ni alloy is in the lower diagram. Both alloys show a general trend of increasing fatigue life with decreasing test temperature in the highest and intermediate strain-amplitude regions. In the higher Ti alloy the fatigue-endurance limit increases with decreasing temperature below A_f. The fatigue limit is insensitive to temperature for the Ti-50.0at%Ni alloy above A_f and for all conditions for the Ti-50.9at%Ni.

Miyazaki *et al.* [27] carefully studied the details of tensile stress–strain curves, to gain insight into the fundamental mechanisms that influence fatigue behaviour and give rise to the differences observed in Figure 13. They measured the proportional stress limit (σ_{pr}) and the critical stress to induce the martensitic transformation (σ_M) and corresponding strains, as schematically illustrated in Figure 14. Below the proportional limit strain (ε_{pr}) there is pure elastic deformation, whereas between ε_{pr} and the elastic limit strain (ε_e) there is an elastic deformation, including microscopic local twinning or microscopic

local stress-induced transformation. The authors further note that the difference between ε_{pr} and ε_e is small below A_f and increases with increasing temperature above A_f, especially for the Ti-50.0at%Ni alloy.

The differences in the fatigue behaviour of these wires can be further understood by considering the mechanisms of the phase deformation. Above A_f, deformation occurs by stress-induced martensite, which is the most severe among the modes tested. Between A_s and A_f deformation is partial stress-induced martensite and partial twinning of the martensite. Testing just below A_s gives rise to a different mode of deformation. In this case, the first cycle is stress-induced martensite, followed by twinning of the martensite. At the lowest test temperatures, deformation is accommodated by martensitic twinning. It is interesting that the fatigue-crack propagation behaviour of Ti–Ni alloys is also differentiated by the details of the deformation mode. Dauskardt *et al.* [29] observed that fatigue-crack growth rates were much slower in fully martensitic Ti–Ni alloys than in alloys that undergo a stress-induced transformation.

Since Nitinol alloys perform better under strain control than under load control, most fatigue studies plot fatigue life as a function of strain, as shown in Figure 13. However, deformation stresses also affect fatigue life, so it is also necessary to compare the fatigue behaviour in terms of stress. In particular, the stress endurance limit for the alloys can be related to the test temperature. For example, the Ti-50.9at%Ni fatigue data from Figure 13 are re-plotted in Figure 15 as a function of stress. The stress endurance limits from both alloys show a linear relationship when

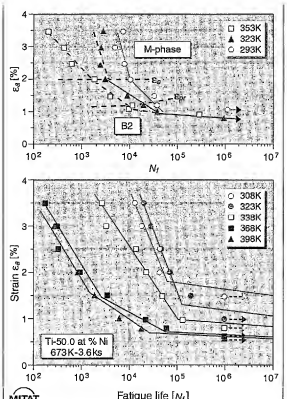

Figure 13. This figure shows the effect of applied strain on the rotary bending fatigue life for Ti-50.9at%Ni (top) and Ti-50.0at%Ni (bottom) alloys at various test temperatures. The endurance limit tends to increase with decreasing test temperature. (After Miyazaki *et al.* Refs 26 and 27.)

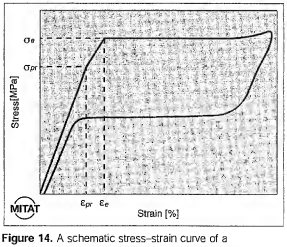

Figure 14. A schematic stress–strain curve of a superelastic Ni-Ti alloy that illustrates the proportional stress limit (σ_{pr}) and the critical stress to induce the martensitic transformation (σ_M) and corresponding strains.

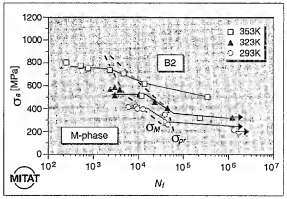

Figure 15. The data from Figure 13 are re-plotted to show the influence of stress on the fatigue life of Ti-50.9at%Ni alloys. Note that the stress endurance limit is a function of test temperature. The proportional stress limit (σ_{pr}) and the critical stress to induce the martensitic transformation (σ_M) are indicated on the figure. (After Kim and Miyazaki, Ref. 26.)

plotted against the difference between test temperature and transformation temperature, T-A_f. As highlighted by Stöckel [2], analysis of the delta between the test temperature and transformation temperature can be a powerful design tool. For example, we can extrapolate the data from constant A_f material tested at different temperatures to understand the behaviour of different transformation temperatures at a constant (body) temperature.

Conclusions

The goals of this paper were to correlate the properties of Ti–Ni alloys with processing, and to address three relevant questions frequently posed by design engineers. Optimised Ti-50.8at%Ni wire was manufactured according to industry standards by precise control of the composition, cold work and continuous strain-age annealing. We can summarise the details presented here by answering the questions posed in the introduction:

Are the mechanical properties constant over a wide range of temperatures?

As shown in Figure 5, the mechanical properties vary over a 300°C temperature range (−100°C to 200°C). Measurement of the permanent set provides a 'superelastic window' where there is minimal residual strain. Within this window, it was also demonstrated that the plateau stresses are directly related to the test temperature and transformation temperature. Therefore, the plateau stress of wire can be readily determined for a given A_f temperature. It was also discussed that the corollary is also true: for a given test temperature, the plateau stresses can be calculated for wires with different transformation temperatures. The important message from this is that the A_f, test temperature, and wire 'stiffness' can not be manipulated independently.

Can we adjust the transformation temperature without modifying the mechanical properties?

As discussed in the previous question, thermal treatments that modify the A_f temperature will also affect the other mechanical properties, especially the plateau stresses. It was shown, however, that the transformation temperature, and hence the properties, can be accurately tuned by selective ageing treatments.

Do the shape-memory and superelastic properties imply that Nitinol has an infinite fatigue life?

The fatigue properties of Ti–Ni wire were shown to depend on the mode of deformation, which, in turn, is a function of the relative stress, strain and test temperature. Higher endurance limits were found for the lowest test temperature conditions. It is recommended that fundamental fatigue tests be run in conjunction with pulsatile testing of medical devices.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/707,685	11/07/2000	Julio C. Palmaz	6006-015	9696

7590 09/30/2008

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EXAMINER	
MILLER, CHERYL L	

ART UNIT	PAPER NUMBER
3738	

MAIL DATE	DELIVERY MODE
09/30/2008	PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte
JULIO C. PALMAZ, STEVEN R.BAILEY
CHRISTOPHER T. BOYLE, and CHRISTOPHER E. BANAS

Appeal 2008-1316
Application 09/707,685
Technology Center 3700

Decided: September 29, 2008

Before TONI R. SCHEINER, ERIC GRIMES, and LORA M. GREEN, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method of manufacturing an endoluminal stent. The Examiner has rejected the claims as anticipated. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

Claims 39-53 and 67-74 stand rejected under 35 U.S.C. § 102(e) as anticipated by Whitcher (Publication No. US 2003/0018381 A1, published January 23, 2003).[1]

As the claims have not been argued separately, and therefore stand or fall together, we select claim 39 as representative of the claimed subject matter for the purpose of deciding all issues raised by this appeal. 37 C.F.R. § 41.37(c)(1)(vii).

Claim 39 is as follows:

39. A method of manufacturing an endoluminal stent capable of radially expanding from a first diameter to a second diameter, and having a plurality of first structural elements defining a longitudinal axis of the stent and a plurality of second structural elements interconnecting adjacent pairs of first structural elements and defining a circumferential axis of the stent, comprising the steps of:

a. vacuum depositing a stent-forming metal onto an unpatterned, exterior surface of a generally cylindrical substrate to form a generally tubular, unpatterned crystalline metal film under vacuum deposition process conditions selected to minimize formation of chemical and intra- and intergranular precipitates in the bulk material;

b. defining the plurality of first and second structural elements of the endoluminal stent in the unpatterned metal film; and

c. removing the endoluminal stent from the generally cylindrical substrate.

Thus, claim 39 requires vacuum deposition of a crystalline metal film onto a substrate, under conditions that minimize the formation of chemical and intra- and intergranular precipitates in the bulk material.

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[1] The rejection of claims 39-53 and 67-74 under 35 U.S.C. § 112, first paragraph, has been withdrawn by the Examiner (Ans. 3).

ISSUE

Appellants contend that Whitcher "does not teach, expressly or implicitly, the step of vacuum depositing a stent-forming metal onto a substrate under process conditions selected to minimize (or substantially eliminate) formation of chemical and intra- and inter-granular precipitates in the bulk material of . . . [an] as-deposited crystalline film" (App. Br. 8).

The Examiner contends that Appellants' "disclosure points simply to a vacuum deposition process (sputtering and ion-bean evaporation . . .) *as the means for minimizing precipitates and other material properties*" (Ans. 4-5), and Whitcher "dislose[s] use of the same vacuum deposition processes . . . and the use of the same materials used by the applicant . . . and discloses [that] such processes control material properties" (*id.* at 5). Therefore, the Examiner contends, "inherently Whitcher is controlling and minimizing material properties such as granular precipitates" (*id.*).

The sole issue raised by this appeal, then, is whether the evidence of record supports the Examiner's assertion that Whitcher's vacuum deposition process inherently minimizes formation of chemical and intra- and inter-granular precipitates in the bulk material of a deposited crystalline film.

FINDINGS OF FACT

FF1. "The present invention consists generally of an endoluminal stent . . . formed from generally two interconnecting structural regions. First structural regions define circumferential sections of the endoluminal stent . . . arrayed in adjacent, spaced-apart relationship with one another along the longitudinal axis of the endoluminal stent. Second structural regions define longitudinal support sections that interconnect adjacent circumferential

sections . . . and are arrayed about the circumference of the endoluminal stent" (Spec. 4: 3-16).

FF2. "The inventive stent . . . is preferably made of a bulk material having controlled heterogeneities on the luminal surface thereof" (Spec. 10: 22-24). "[H]eterogeneities are controlled by fabricating the bulk material of the stent to have defined grain sizes, chemical and intra and intergranular precipitates" (Spec. 10: 26-28).

FF3. According to the Specification, "physical properties, including . . . elasticity, tensile strength, mechanical properties, hardness, bulk and/or surface grain size, grain composition, and grain boundary size, intra and inter-granular precipitates" are encompassed by the term "material properties" (Spec. 10: 13-16).

FF4. The Specification teaches that "the foregoing properties are achieved by fabricating a stent by the same metal deposition methodologies as are used and standard in the microelectronics and nano-fabrication vacuum coating arts . . . The preferred deposition methodologies include ion-beam assisted evaporative deposition and sputtering techniques" (Spec. 11: 11-15).

FF5. "In ion beam-assisted evaporative deposition it is preferable to employ dual and simultaneous thermal electron beam evaporation with simultaneous ion bombardment of the substrate using an inert gas, such as argon, xenon, nitrogen or neon . . . [which] serves to reduce void content . . . [and] allows the mechanical properties of that deposited material to be similar to the bulk material properties" (Spec. 11: 15-22).

FF6. "Alternate deposition processes which may be employed to form the stent . . . are cathodic arc, laser ablation, and direct ion beam deposition" (Spec. 11: 28-30).

FF7. According to the Specification, "[v]apor deposition of the inventive endoluminal stent . . . significantly reduces or virtually eliminates inter- and intra-granular precipitates in the bulk material" and "the need to control precipitates for mechanical properties is eliminated" (Spec. 14: 19-25).

FF8. There are no working examples in the present Specification, but the Specification indicates that "[m]aterials to make the inventive stents . . . include the following: elemental titanium, . . . nickel, tantalum, zirconium, . . . and alloys thereof, such as zirconium-titanium-tantalum alloys, nitinol, and stainless steel" (Spec. 12: 5-10). In addition, the Specification teaches that "the chamber pressure, the deposition pressure and the partial pressure of the process gases are controlled to optimize deposition of the desired species onto the substrate. As is known in the . . . vacuum coating arts, both the reactive and non-reactive gases are controlled and the inert or non-reactive gaseous species introduced into the deposition chamber are typically argon and nitrogen" (Spec. 12: 11-16). "The deposited material maybe deposited either as a uniform solid film onto the substrate, or patterned" (Spec. 12: 18-19).

FF9. Whitcher teaches that "conventional processes used to produce patterned stents often start with wire, tube or sheet materials" and typical processing steps include winding, welding, heat treating, stamping, cutting, etching, expanding, and/or rolling the material to create the final device

(Whitcher ¶ 3). According to Whitcher, "[m]ost of the manufacturing steps associated with these conventional methods introduce defects into the metallic structure of the formed device" (Whitcher ¶ 4), for example, localized deformation and surface flaws (*id.*).

FF10. According to Whitcher, "[s]ome defects in the formed device may be reduced by techniques, such as annealing, but these techniques often impart other undesirable effects. For instance, annealing often requires high temperature treatment of a metallic device to recrystallize its microstructure to reduce grain size . . . Such a high temperature treatment can often impart physical deformation of the device" (Whitcher ¶ 5).

FF11. Whitcher describes a method of manufacturing medical devices, including radially expandable intraluminal stents with interconnected longitudinal and circumferential structural elements (Whitcher ¶ 45, Figs. 1, 2), "having improved mechanical properties" (Whitcher ¶ 8). According to Whitcher, "the difficulties associated with conventional medical devices and the methods used to form such medical devices" can be overcome "[b]y using vapor deposition techniques" to "accurately and precisely control[ ]" "the composition, thickness, surface roughness, and microstructure" of the medical devices (Whitcher ¶ 28).

FF12. According to Whitcher, "[t]he medical devices formed by the process of . . . [vapor deposition] are tailored to have desired compositions, mechanical properties, and geometries" (Whitcher ¶ 28). Further, a metallic layer "can be formed to have a range of crystalline morphologies, including a monocrystalline or nanocrystalline morphology" using vapor deposition techniques (Whitcher ¶ 48).

FF13. According to Whitcher, "[e]xamples of useful vapor deposition processes . . . include physical vapor deposition processes such as evaporation and sputtering. Direct and assisted ion beam deposition, and chemical vapor deposition are also useful" (Whitcher ¶ 34).

FF14. Whitcher teaches that "[t]he material deposited as the metallic layer [on a mandrel] . . . is any suitable material for use in medical device applications, such as . . . nitinol, stainless steel, titanium, [etc.] . . . The vapor deposition of these materials results in a deposited metallic layer . . . having a fine, equiaxed microstructure which may be precisely established as a function of process parameters. These microstructures in turn affect mechanical properties such as strength and corrosion resistance" (Whitcher ¶ 62). "After release from the mandrel . . . the metallic layer . . . either serves as a stent or as the basis for forming a stent" (Whitcher ¶ 54).

FF15. In Example 1 of Whitcher, an equiaxed, nanocrystalline, "patterned nitinol stent is formed according to the following processing steps" (Whitcher ¶¶ 66, 67):

> A steel wire mandrel measuring about 10 mm in diameter and 30 mm in length is placed in a vacuum chamber . . . Also mounted in the chamber is a nitinol source target comprising about 55.9 wt % nickel and the balance essentially titanium. The chamber is then evacuated to a pressure of less than 10^{-6} torr. Argon is introduced into the chamber at a flow rate . . . producing an operating pressure of about 10 millitorr. A plasma is then generated in the chamber by ion bombardment of the nitinol target, resulting in nitinol deposition onto the wire mandrel. Sputter deposition is continued until the thickness of the deposited nitinol layer is about 0.25 mm, after which the coated mandrel is removed from the chamber.

> The coated mandrel is cut at both ends to a length of about 20 mm. A pattern is formed in the coated mandrel by machining oval-shaped holes through the thickness thereof. The deposited nitinol layer is removed from the mandrel by dissolving the mandrel in hydrochloric acid thus yielding a functional nitinol stent with a fine, equiaxed and nanocrystalline microstructure. . . . A grain size of the nanocrystalline structure is measured to be less than 10 nanometers by this technique.

(Whitcher ¶¶ 66, 67). Examples 2-5 describe additional vapor deposition processes that produce a nitinol layer in nanocrystalline form.

FF16. As an alternative to initial deposition of a crystalline layer, Whitcher describes "[a]nother useful method . . . for forming medical devices . . . [by] crystallization of structures formed with an amorphous morphology" (Whitcher ¶ 41). "The amorphous structure may subsequently be treated or aged under conditions that are well below typical annealing temperatures . . . to form a monocrystalline metallic structure" (*id.*). Whitcher also teaches that another "useful method for forming such [nanocyrstalline] structures is through epitaxy where desired material is deposited [as an amorphous layer] onto a substrate having a crystalline structure, such as an orientated, nanocrystalline structure, and the deposited material forms a crystalline structure similar to that of the substrate" (Whitcher ¶ 43).

DISCUSSION

The Examiner rejected claims 39-53 and 67-74 under 35 U.S.C. § 102(e) as anticipated by Whitcher.

Whitcher describes a method of manufacturing a metallic, radially expandable endoluminal stent with interconnecting longitudinal and circumferential structural elements (FF11). The Examiner acknowledges that "Whitcher does not explicitly recite [minimizing] granular precipitates" (Ans. 5), but contends that Whitcher's method inherently minimizes formation of chemical and intra- and intergranular precipitates in the bulk material, because Whitcher discloses "the same vacuum deposition processes (sputtering, ion beam deposition . . .) and the use of the same materials used by the applicant . . . and discloses such processes control material properties" (*id.*). "Further, Whitcher specifically discloses *accurately and precisely controlling* the composition and microcrystal structure to have the desired mechanical properties" (*id.*), by "selection of a temperature, pressure, and rate during deposition, therefore, inherently the precipitates are being controlled, since amount and size of the granular precipitates are dependent upon temp, pressure, and rate (general process conditions of vacuum deposition, which applicant has disclosed to be the method of minimizing precipitates)" (*id.*).

We find no error in the Examiner's conclusion that Whitcher anticipates the claimed invention, based on the evidence of record. The present Specification indicates that the material properties of a crystalline metal film, including "surface grain size, grain composition, and grain boundary size, intra and inter-granular precipitates" (Spec. 10: 15-16; FF3), "are achieved by fabricating a stent by the same metal deposition methodologies as are used and

standard in the microelectronics and nano-fabrication vacuum coating arts" (Spec. 11: 11-13; FF4), preferably "ion-beam assisted evaporative deposition and sputtering techniques" (Spec. 11: 14-15; FF4). No working examples or specific vacuum deposition conditions are described in the Specification (FF8). Rather the Specification merely indicates that the choice of vapor deposition to manufacture metallic stents "significantly reduces or virtually eliminates inter- and intra-granular precipitates in the bulk material" (Spec. 14: 19-21; FF7).

Appellants acknowledge that Whitcher discloses "physical vapor deposition processes of evaporation and sputtering . . . [and] direct and assisted ion beam deposition and chemical vapor deposition" (App. Br. 9), but contend that Whitcher "does not qualify as an enabling prior art reference with regard to . . . [the] pending claims" (App. Br. 16). Appellants argue that Whitcher

> offers no guidance or teaching that any of these processes may be employed to form an as-deposited crystalline film . . . while controlling the deposition process to minimize precipitate formation. The reference merely states the specific conditions selected, *i.e.*, chamber pressure, deposition rate, without any suggestion that those conditions may be controlled in such a manner as to minimize precipitate formation in a crystalline film . . . In fact, none of the Examples found in *Whitcher* contain any statement or suggestion either that 1) the vacuum deposited film is crystalline or 2) precipitate formation has, in fact, been controlled.

(App. Br. 9.)

This argument is not persuasive. First, Whitcher explicitly describes vapor deposition of monocrystalline and nanocrystalline metallic films (FF15). Second, while Whitcher does not specifically mention selecting deposition conditions to minimize precipitate formation, again, the present Specification

merely indicates that the choice of vapor deposition to manufacture metallic stents "significantly reduces or virtually eliminates inter- and intra-granular precipitates in the bulk material" (Spec. 14: 19-21; FF7). Given this teaching in the Specification, the lack of any other disclosure in the Specification regarding deposition conditions (FF8), and the fact that Whitcher describes a method of making stents using the same materials taught by Appellants, and the same vacuum deposition processes taught by Appellants (FF13, 14), to control "the composition, thickness, surface roughness, and microstructure" of the medical devices" and impart "desired compositions, mechanical properties, and geometries" (FF11, 12), we find that the evidence of record supports the Examiner's conclusion that "inherently the precipitates are being controlled" in Whitcher's vacuum deposition method (Ans. 5).

Appellants also argue that Whitcher "teaches depositing a material onto a substrate in its amorphous state and after deposition treating or aging the amorphous structure (as expressly taught in Paragraph 0041) to form either a monocrystalline or nanocrystalline structure" (App. Br. 13). Appellants contend that "[t]his is, without question, different and distinct from the presently claimed invention wherein a film is vacuum deposited as a crystalline layer onto the substrate under conditions which minimize precipitate formation" (App. Br. 13).

We are not persuaded. Paragraph 41 of Whitcher describes "[a]nother useful method" of forming a stent, in which a metallic film is initially deposited as an amorphous layer, and subsequently crystallized (Whitcher ¶ 41, FF16). As discussed above, this is described as an alternative to vapor

deposition of nanocrystalline nitinol films (FF15, 16). Moreover, Whitcher clearly distinguishes between amorphous and crystalline films (FF16).

Similarly, Appellants argue

> [i]n contrast to the conventional nitinol vacuum deposition process described in *Whitcher*, the claimed method eliminates the need for an annealing step. The claimed method achieves this by providing means for vacuum depositing a thin film that is in crystalline form as deposited. As a result, an annealing step is not required, and no precipitates are thereby formed. Thus, Applicants teach a method for minimizing precipitate formation that is distinguished from and not taught by *Whitcher*.

(App. Br. 12.)

Again, this argument is not persuasive. Whitcher explicitly avoids annealing processes by vacuum deposition of an "as deposited" crystalline metallic film which needs no annealing (FF10, 11, 15).

Having considered the respective positions of Appellants and the Examiner, we find that the Examiner has established a prima facie case of anticipation of the claimed invention, which Appellants have not overcome by argument or evidence. We therefore affirm the Examiner's rejection of the claims as anticipated by Whitcher.

SUMMARY

The rejection of claims 39-53 and 67-74 under 35 U.S.C. § 102(e) as anticipated by Whitcher is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

LP

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,146	11/17/2000	Christopher T. Boyle	6006-018	6734

7590 04/30/2008

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EXAMINER	
MILLER, CHERYL L	

ART UNIT	PAPER NUMBER
3738	

MAIL DATE	DELIVERY MODE
04/30/2008	PAPER

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The time period for reply, if any, is set in the attached communication.

DOCKETED
By: SMC Date: 5-5-08
Due: 6-30-08
1. NOTICE OF APPEAL
2. REQUEST FOR RENEWING
3. AMENDMENT V ECE.

DECISION DOCKETED IN:
009 070 107
015 077

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte CHRISTOPHER T. BOYLE

Appeal 2007-3212
Application 09/716,146
Technology Center 3700

DECIDED: April 30, 2008

Before TONI R. SCHEINER, ERIC GRIMES, and LORA M. GREEN, *Administrative Patent Judges.*

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 16, 20, and 26-28, all the claims remaining in the application. The claims stand rejected as anticipated by the prior art. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

STATEMENT OF THE CASE

"[T]he present invention relates to . . . an endoluminal stent . . . having cavitated regions with micropores that communicate a bioactive agent from the cavity to an area external the stent" (Spec. 1: 10-13).

Claims 16 and 20 are representative, and read as follows:

16. An endoluminal stent for delivering a bioactive agent to a situs in a body, comprising:

a plurality of structural elements forming a radially expandable cylindrical member, the plurality of structural elements having a wall thickness; wherein the structural elements are fabricated of a metal and comprising a base layer and a second layer covering the base layer, further comprising a void space intermediate the base and second layers and enclosed therebetween;

a plurality of pores passing through at least one of the base and second layers and communicating with the void space; and

at least one bioactive agent retained within the void space and elutable through the plurality of pores.

20. The endoluminal stent according to claim 16, further comprising a degradable plug residing within the plurality of pores to prohibit release of the at least one bioactive agent until the degradation of the degradable plug.

The claims stand rejected as follows:

I. Claims 16, 20, and 26-28 under 35 U.S.C. § 102(e) as anticipated by Brown (U.S. Patent 6,071,305, issued June 6, 2000).

II. Claims 16, 26, and 27 under 35 U.S.C. § 102(b) as anticipated by Monaco (International Patent Application WO 94/18906, published September 1, 1994).

III. Claims 16, 20, and 26-28 under 35 U.S.C. § 102(b) as anticipated by Yan (U.S. Patent 5,843,172, issued December 1, 1998).

IV. Claims 16, 26, and 27 under 35 U.S.C. § 102(b) as anticipated by Buirge (U.S. Patent 5,735,897, issued April 7, 1998).

FINDINGS OF FACT (FF)

1. Claim 16 on appeal is directed to a radially expandable endoluminal stent made up of a plurality of structural elements, where the structural elements "are fabricated of a metal and compris[e] a base layer and a second layer covering the base layer," i.e., both the base layer and the second layer are made of metal, with void space between the base and second layers, and pores in the base and/or second layer communicating with the void space. The void space contains a bioactive agent, which is elutable through the pores.

2. According to the Specification, "either forming wrought metal parts, such as capillary tubing, into the implantable device or forming the implantable devices by vacuum deposition techniques . . . [is] the preferred method of making the implantable structural elements" of the stents (Spec. 10: 18-20).

3. "Where an implantable device is to be formed from non-preexisting structural elements, vacuum deposition techniques may be employed to form the implantable structural body, such as sputtering, reactive ion etching, chemical vapor deposition, plasma vapor deposition, or the like" (Spec. 11: 2-5). Internal cavities and openings can be formed by depositing patterned sacrificial material "over a base layer of structural material, then depositing a second layer of structural material over the sacrificial material and the base layer" and removing the sacrificial material "to leave the internal cavities

and plurality of openings formed within the deposited bulk material" (Spec. 11: 10-13).

4. The stents are "preferably formed of a metal such as titanium . . . or stainless steel" (Spec. 8: 23-26).

5. "Because of their use as a structural scaffold and the requirement that stents be delivered using transcatheter approaches, stents necessarily are delivered in a reduced diametric state and are expanded or allowed to expand *in vivo* to an enlarged diametric state" (Spec. 5: 7-9).

Brown

6. Brown describes "a biologically active agent delivery stent" which is "expandable for supporting a body lumen" (Brown, col. 2, ll. 53-55).

7. Brown describes an expandable stent "formed from an elongated or tubular member . . . in the shape of a coil or helix" (Brown, col. 5, ll. 39-42), or "other configurations such as . . . expandable tube stents, roving wire stents, and wire mesh stents. Thus, the elongated member . . . may be the filaments or fibers which form a mesh stent" (Brown, col. 7, ll. 36-39).

8. The stents may be formed from "a biocompatible metal or alloy such as stainless steel, [or] titanium" (Brown, col. 7, ll. 15-16; col. 12, ll. 7-8).

9. For clarity, Brown's Figure 2 is reproduced immediately below:

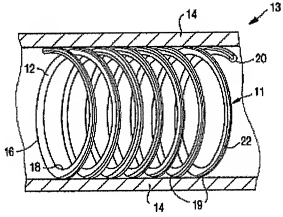


Figure 2 "is a cross sectional side view of a body lumen and a perspective view of a stent" (Brown, col. 3, ll. 62-63), "formed from an elongated or tubular member **12** . . . in the shape of a coil or helix" (Brown, col. 5, ll. 39-42).

10. "The tubular or elongated member **12** of the directional drug delivery stent **11** . . . is formed with an interior or cavity **20** . . . extending along the entire length of the elongated member" (Brown, col. 5, ll. 46-52), and "has a fluid opening or delivery means for directionally delivering a biologically active agent within the cavity or interior **20** . . . the fluid opening or delivery means may be a slit shaped opening **22** extending along the outer surface **16** of the stent which allows the active agent to be delivered from the cavity **20**" (Brown, col. 6, ll. 7-13). Alternatively, the fluid opening or delivery means may be "a series or plurality of holes, grooves, small indentations, . . . [or] intermittent recessions" (Brown, col. 6, ll. 15-16).

11. For clarity, Brown's Figure 5 is reproduced immediately below:

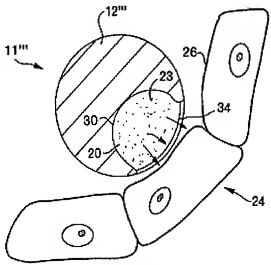


FIG. 5

Figure 5 "is an enlarged cross-sectional view of the elongated member [**12**] . . . positioned in a body lumen" (Brown, col. 4, ll. 8-11). Cavity **20** contains a biologically active agent **23**, and "membrane **34** . . . covers the slit shaped opening and allows the active agent to diffuse through the membrane to the desired predetermined location" (Brown, col. 9, ll. 13-15). Suitable membranes **34** include "poly-ethylene-vinyl acetate, polyethylene, polyesters, [etc.]" (Brown, col. 9, ll. 19-20).

12. For clarity, Brown's Figure 7 is reproduced immediately below:

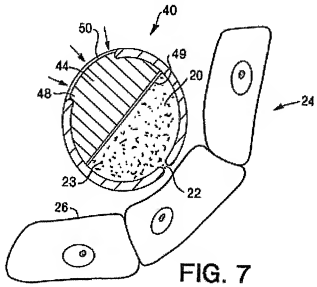


FIG. 7

Figure 7 "is an enlarged cross-sectional view of the elongated member [of] an osmotic directional delivery stent . . . positioned in a body lumen" (Brown, col. 4, ll. 16-18). "[T]he tubular member of the stent **40** is provided with a fluid inlet opening **48** which allows fluid from . . . the interior of the body lumen **24** to enter the osmotic agent **44** causing it to swell. The osmotic agent may be an osmagent, an osmopolymer, or a mixture of the two" (Brown, col. 9, ll. 43-48). The elongated member "also includes an optional separating member **49** between the osmotic agent **44** and the

biologically active agent **23** . . . [which] keeps the osmotic agent **44** separate from the biologically active agent **23** while also allowing the osmotic agent to swell. The separating member **49** may be . . . made of a flexible material that stretches as the osmotic agent imbibes fluid" (Brown, col. 10, ll. 43-51).

Monaco

13. Monaco describes an artificial organ that includes "a first housing having at least one interior and at least one exterior surface. The interior surface(s) define a chamber and the exterior and interior surfaces are in fluid communication with each other" (Monaco 3), and "the interior and exterior surfaces in closest facing relationship to each other are perforated" (*id.*). "A membrane is disposed within the chamber, at least a portion of the membrane being selectively permeable to bodily fluids. The membrane contains one or more cells . . . capable of producing a biological agent" (*id.*). "The selectively permeable membrane allows . . . body fluids to pass through . . . and permits a biological agent produced by the cells to pass through the membrane" as well (*id.*).

14. The first housing "can be comprised of, for example, stainless steel, [or] titanium" (Monaco 8), and can be "of sufficient thickness and of sufficient inflexibility to protect [the] membrane . . . from breakage" (*id.*).

15. Monaco's Figure 8 illustrates an artificial organ comprising "a pair of concentrically arranged [cylindrical] housings that are accessible to bodily fluids" (Monaco 20). Figure 8 is reproduced immediately below:

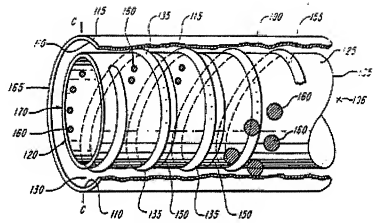


FIG. 8

Figure 8 "is a partial cut-away view of . . . [an] implantable artificial organ" (Monaco 6), in which "[a] substantially annular volume **130** is defined between the interior surface **110** of first housing **100** and exterior surface **125** of second housing **105**. Disposed within volume **130** is a selectively permeable membrane **135**" (Monaco 21), and "[c]ells **155** capable of releasing a biological agent, are disposed within the selectively permeable membrane **135**" (*id.*).

Yan

16. Yan describes an intra-vascular, radially-expandable stent that delivers a therapeutic agent to the site of implantation (Yan, col. 1, ll. 8-10).

17. The stent "is made of metal and has porous cavities in the metallic portion of the prosthesis so that . . . drugs can be loaded directly into the pores without substantially weakening the structural and mechanical characteristics of the prosthesis" (Yan, col. 1, ll. 63-67).

18. "[T]he porous cavities of the stent can be formed by sintering the stent material from metallic particles, filaments, fibers or other materials. The stent can be formed from a sintered wire . . . [or] from a sintered cylindrical

tube or sintered metal sheet which can be laser cut or chemical[ly] etched into an expandable stent structure" (Yan, col. 2, ll. 7-14).

19. Yan's Figure 12 illustrates a sheet that can be cut or etched into a stent configuration (Yan, col. 8, ll. 64-65). Figure 12 is reproduced below:

FIG. 12

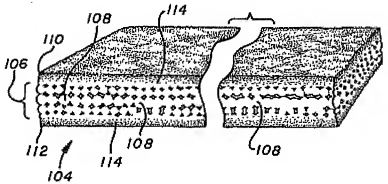


Figure 12 is a cross-sectional, partially cut away view of "a sintered sheet **104** of metal having a core **106** formed of large diameter particles **108** that form large pores. The core layer **106** is sandwiched between two layers **110** and **112** formed of smaller diameter particles **114** that form smaller diameter pores. Such a sheet is formed by orienting a middle or core layer **106** of large diameter particles along a plane. A top layer of smaller diameter particles is arranged in a plane parallel to and above the middle layer. A bottom layer of particles are arranged in a plane parallel to and below the middle layer. The three layers are pressed together and sintered into a single sheet" (Yan, col. 3, ll. 49-50, col. 8, ll. 53-64).

20. Yan's Figure 10 illustrates another sheet that can be formed into a stent by "loop[ing] [it] into a cylindrical formation" (Yan, col. 8, ll. 30-31). Figure 10 is reproduced immediately below:

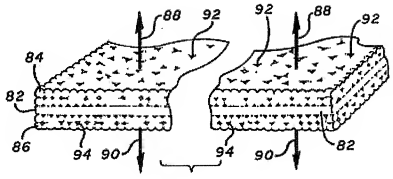


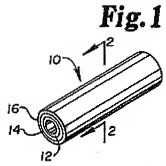
FIG. 10

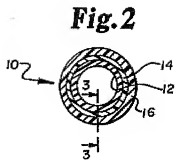
Figure 10 is a cross-sectional, partially cut away view of a "sheet formed of sintered particles that are sintered to both sides **84** and **86** of a metal sheet **82**" (Yan, col. 8, ll.15-16). "[A] therapeutic agent loaded into the pores **92** on the top side of **84** the sheet permeates . . . outward from the solid core. A therapeutic agent loaded into the pores **94** on the bottom side **86** . . . permeates . . . [in the opposite] direction **90**" (Yan, col. 8, ll. 22-39).

21. Yan's stent can be coated with a bioabsorbable, polymeric "coating **100** [that] dissolves after implantation and . . . delays the time that a therapeutic agent is released into the vasculature of a patient. The thickness of the coating as well as the rate at which the coating is bioabsorbed determines the length of time . . . before a therapeutic agent is delivered from the pores of the stent" (Yan, col. 9, ll. 51-59).

Buirge

22. Buirge describes "an expandable stent-like structure which may be expanded in situ to fit the vessel in which it is being placed" (Buirge, col. 5, ll. 27-28), illustrated in Figures 1, 2, and 3, which are reproduced immediately below:





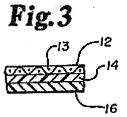


Figure 1 "is a schematic showing of the stent-like vascular prosthesis" (Buirge, col. 1, ll. 64-65); Figure 2 "is a cross-section view of the prosthesis of FIG. 1 taken along line 2—2" (*id.*, col. 1, ll. 66-67); Figure 3 "is a cross-section of the prosthesis of FIG.1 taken along line 3—3 of FIG. 2" (*id.*, col. 2, ll. 1-2).

23. Referring to Buirge's Figures 1, 2, and 3, layer **16** is the outer layer of the prosthesis; layer **14** is "the intermediate drug bearing layer"; and layer **12** is the "inner, bodily fluid contacting layer" (Buirge, col. 4, l. 66 to col. 5, l. 12).

24. Layers **12** and **16** of the stent-like prosthesis may be "[m]etals such as stainless steel and nitinol . . . in either a fixed diameter or expandable configuration" and "[f]urthermore, . . . may be in a mesh form, a screen form

or a filamentary form" (Buirge, col. 5, ll. 35-45). "[I]nner layer **12** may be rendered permeable by including openings therein of a size selected to provide any desired flow through rate and diffusion rate" (*id.*).

DISCUSSION

Brown

Claims 16, 20, and 26-28 stand rejected under 35 U.S.C. § 102(e) as anticipated by Brown. We will reverse this rejection.

The Examiner contends that Brown discloses several expandable endoluminal stents, specifically those shown in Figures 5, 7, 8, 10, and 12 "having the layers as claimed" (Ans. 5). For example, the Examiner finds that the embodiment shown in Brown's Figure 5 has a base layer **12** and a second layer **34**. As discussed above, Figure 5 shows the elongated member with a cavity **20** containing a biologically active agent **23**, covered by membrane **34**, which allows the active agent to diffuse out of the slit shaped opening (FF 11). Thus, elongated member **12** (characterized as a base layer by the Examiner) can be made of metal (FF 8), while membrane **34** (characterized as a second layer by the Examiner) is not (FF 11).

Similarly, the Examiner finds that the embodiment shown in Brown's Figure 7 has a base layer **40** and additional layers **44** and **49**, with a void layer **20** in between. As discussed above, according to Brown, **40** is the tubular member of a stent, while **44** is an osmotic agent that operates by imbibing fluid from the biological environment, swelling, and pressing on the flexible separating member **49**, compressing active agent **23** within cavity **20**, and ultimately pushing the active agent out of slit shaped opening **22** (FF 12). Tubular member **40** (characterized as a base layer by the

Examiner) may be made of metal (FF 8), but osmotic agent **44** and separating member **49** (characterized as additional layers by the Examiner) are not (FF 12).

Essentially, Appellant contends that Brown does not anticipate the claimed invention because claim 16, the only independent claim on appeal, "requires that the base and second layer be made of metal" (App. Br. 8).

The Examiner, on the other hand, contends that "the structural elements [of the claimed stent] are claimed to be fabricated of metal, [but] the 'layers' are not required . . . to be metal; that is the structural elements as a whole need only *comprise* metal and may include other materials as well" (Ans. 5).

We agree with Appellant that "use of the 'comprising' language modifies the base layer and the second layer, not [the] structural element or the metal" (App. Br. 7-8). "Thus, the claim may reasonably be interpreted as requiring at least a base layer and a second layer, . . . [and] could have other components, e.g., a third layer" as well (App. Br. 8), but the claim "requires that the base and second layer be made of metal" (App. Br. 8).

Brown does not describe a stent with a metal base layer and a second layer, also made of metal, wherein the base and second layers enclose a void space containing an active agent, and therefore, does not anticipate the claimed invention.

The rejection of claims 16, 20, and 26-28 under 35 U.S.C. § 102(e) as anticipated by Brown is reversed.

Monaco

Claims 16, 26, and 27 stand rejected under 35 U.S.C. § 102(b) as anticipated by Monaco. We will reverse this rejection.

Monaco describes an artificial organ comprising "a pair of [cylindrical] concentrically arranged housings that are accessible to bodily fluids" (Monaco 21, FF 15).

According to Appellant, endoluminal stents are "delivered using transcatheter approaches, so stents are delivered in a reduced diametric state and are expanded or allowed to expand in vivo to an enlarged diametric state" (Reply Br. 16). Appellant contends "there is no explicit or implicit limitation [sic, evidence?] that the Monaco artificial organ is radially expandable" (App. Br. 21). Thus, Appellant contends that Monaco does not meet "Claim 16's radially expandable limitation" (App. Br. 21).

The Examiner, on the other hand, contends that Monaco's cylindrical artificial organ is "radially expandable" because it is made of "titanium or stainless steel, two metals disclosed/admitted by *applicant* to be expandable" (Ans. 6).

We disagree with the Examiner's rationale and conclusion. The mere fact that both Monaco's device and Appellant's device can be made of the same material is not sufficient to establish that Monaco's device is radially expandable. Monaco's device comprises concentric cylindrical housings, with a tubular membrane wrapped around the inner cylindrical housing in a spiral fashion (Monaco Fig. 8; FF 15). The housings "can be comprised of, for example, stainless steel, [or] titanium" (Monaco 8; FF 14), "of sufficient thickness and of sufficient inflexibility to protect [the] membrane . . . from

breakage" (*id.*). The Examiner has not explained how Monaco's device can have a configuration that is inflexible enough to keep the membrane from breaking, and at the same time, be radially expandable.

The rejection of claims 16, 26, and 27 under 35 U.S.C. § 102(b) as anticipated by Monaco is reversed.

Yan

Claims 16, 20, and 26-28 stand rejected under 35 U.S.C. § 102(b) as anticipated by Yan. Appellant presents separate arguments with respect to claims 16 and 20. Claims 26-28 will stand or fall with claim 16, as provided by 37 C.F.R. § 41.37(c)(1)(vii) (2006).

We agree with the Examiner that Yan describes a radially expandable endoluminal stent (FF 16), with a sintered metal base layer (FF 17, 18, 19, 20), and second layer(s), also made of sintered metal (*id.*), with void spaces ("porous cavities") between the base layer and the second layer(s) (FF 18, 19, 20), pores passing through at least one of the base and second layers (FF 19, 20), and a bioactive ("therapeutic") agent loaded into the void spaces and elutable through the pores (FF 16, 17, 18). Moreover, we agree with the Examiner that Yan describes degradable plugs (dissolvable "coating **100**") in the pores that prohibit release of the bioactive agent until degradation of the plug (FF 21).

With respect to claim 16, Appellant argues that "Yan fails to disclose a base layer and second layer covering the base layer" (App. Br. 22), or "a void space intermediate between the layers and enclosed therebetween" (App. Br. 23). According to Appellant, "the outer surface region layers in [Yan's] figure 12 are not layers" (App. Br. 22) because they "are formed by

smaller diameter particles . . . result[ing] in the outer surface region having several thicknesses due to the varying diameter of the smaller particles" (*id.*). Similarly, Appellant argues that "[t]he middle region layer in figure 12 is . . . formed of large diameter particles **108**" (*id.*), thus, "[c]ore **106** would not be a single thickness, because at various points of the perimeter of core **106**, the large diameter particles [**108**] would form a thickness that varies with the circumference of the large diameter particles" (*id.*). In the Reply Brief, Appellant explains that he "has not argued a constant thickness, but rather a single thickness. A single thickness is required by a layer, as a plain and ordinary meaning" (Reply Br. 16).

These arguments are not persuasive. Yan describes the metal sheet shown in Figure 12 as having a core layer made from large diameter sintered particles oriented in a plane, which is sandwiched between two layers of smaller diameter sintered particles oriented in parallel planes on either side of the layer made from the large diameter particles (Yan, col. 8, ll. 53-64). Whether Appellant's contention is that Yan's "layers" are not layers because they are of variable thickness (i.e., they are bumpy, rather than perfectly uniform, flat, and smooth), or that they are not layers because they are not "single" thicknesses, the flaw in the contention is the same. Appellant has not pointed to anything in the Specification or the claims which requires layers of uniform thickness, or layers of a "single" thickness. In any case, once the particles are sintered, they are fused into a single thickness, even if they are several particles deep.

Finally, Yan clearly shows void spaces (small pores and large pores) in fluid communication between the layers, and retaining a bioactive agent

elutable from the top and bottom surfaces of the sheet (FF 19). Moreover, Yan's Figure 10 shows a sheet formed of particles sintered to both sides of a metal sheet, with therapeutic agents loaded into the pores on the top and bottom sides of the sheet, so that the agent in the top side pores elutes through the top particle layer to one side of the sheet, and the agent in the bottom side pores elutes through the bottom particle layer to the other side of the sheet (Yan, col. 8, ll. 15-39; FF 20).

With respect to claim 20, Appellant argues that Yan's dissolvable coating **100** is a "layer of a substance spread over a surface" rather than an "object used to fill a hole tightly" (App. Br. 23).

This argument is not persuasive. Yan's coating prevents release of the bioactive agent from the pores of the stent until after implantation, when the coating is dissolved (FF 21). Clearly, the coating temporarily plugs the pores on the surface of the stent. Appellant has not pointed to anything in the Specification or the claims which requires individual plugs in each pore, or which would exclude a coating layer that plugs multiple pores at the same time.

The rejection of claims 16, 20, and 26-28 under 35 U.S.C. § 102(b) as anticipated by Yan is affirmed.

Buirge

Claims 16, 26, and 27 stand rejected under 35 U.S.C. § 102(b) as anticipated by Buirge. The claims have not been argued separately, so claims 26 and 27 will stand or fall with claim 16, as provided by 37 C.F.R. § 41.37(c)(1)(vii) (2006).

We agree with the Examiner that Buirge describes a radially expandable endoluminal stent (FF 22), with a metal base layer (inner layer **12**) (FF 24), and a second layer (outer layer **16**), also made of metal (FF 24), with a bioactive agent-containing space ("intermediate drug bearing layer" **14**) between the base layer and the second layer (FF 23), and pores ("openings") passing through at least one of the base and second layers (FF 24), such that the bioactive agent is elutable through the pores (FF 24).

Appellant argues that Buirge's "intermediate layer **14** is the drug or therapeutic containing matrix and may be comprised of various aqueous solutions" and "would not be a void, i.e. empty and containing no matter" (App. Br. 24). Therefore, Appellant argues, Buirge does not describe an "intermediate void space enclosed [between]" a base layer and a second layer (App. Br. 25).

This argument is not persuasive. The "void" required by present claim 16 is not "empty and containing no matter" either. Rather the claim requires a void between the base and second layers containing "at least one bioactive agent" (i.e., a bioactive agent-containing reservoir). Buirge's intermediate layer **14** is a "void" in the same sense, i.e., layer **14** is a reservoir containing/retaining a bioactive reagent between inner layer **12** and outer layer **16**.

The rejection of claims 16, 26, and 27 under 35 U.S.C. § 102(b) as anticipated by Buirge is affirmed.

SUMMARY

The rejections of the claims as anticipated by Brown and Monaco are reversed. The rejections of the claims as anticipated by Yan and Buirge are affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

dm

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte CHRISTOPHER T. BOYLE

Appeal 2008-1062
Application 10/258,087
Technology Center 3700

Decided: December 22, 2008

Before TONI R. SCHEINER, ERIC GRIMES, and LORA M. GREEN, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims directed to an endoluminal stent. The claims stand rejected as anticipated. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm-in-part.

STATEMENT OF THE CASE

"[T]he present invention relates to an implantable medical device, such as an endoluminal stent . . . having cavitated regions incorporated within the material of the device with micropores that communicate a bioactive agent from the cavity to an area external the device" (Spec. 1: 13-17).

Claims 5-10 and 15-21 are pending and on appeal. Claims 1-4 and 11-14 have been canceled.

Claims 5, 8, 15, and 19 are representative of the subject matter on appeal:

5. An endoluminal stent, comprising:

a tubular member having a central lumen passing longitudinally through the tubular member and open at opposing ends of the tubular member, a luminal surface and an abluminal surface and a wall thickness defined therebetween, at least one internal cavity residing within the wall thickness in portions of the tubular member that are substantially isolated from stress or strain forces on the endoluminal stent during delivery, a plurality of openings communicating between the at least one internal cavity and at least one of the luminal surface, abluminal surface, proximal end or distal end of the tubular member, and at least one bioactive agent disposed in the at least one internal cavity.

8. An endoluminal stent, comprising:

a cylindrical member comprised of a plurality of interconnected structural elements defining walls of the cylindrical member, a plurality of discontinuous interior cavities disposed completely within at least some of the plurality of structural elements, and a plurality of openings communicating between each of the plurality of discontinuous interior cavities and external the stent, and at least one bioactive agent disposed within the plurality of discontinuous interior cavities.

15. An endoluminal stent for delivering a bioactive agent to a situs in a body, comprising:

a plurality of struts interconnected at a plurality of hinge regions forming a radially expandable cylindrical member, at least some of the plurality of struts being further comprised of a first regions having a first wall thickness and a second region having a second wall thickness, the first region being in proximity to one of the plurality of hinge regions and the second region being substantially isolated from each of the plurality of hinge regions;

at least one void space formed entirely within the second wall thickness of the second region, at least one of a plurality of pores communicating between the at least one void space and through the second wall thickness to at least one surface of the second region and external the endoluminal stent, and at least one bioactive agent retained within the void space and elutable through the at least one of a plurality of pores.

19. A drug eluting stent, comprising:

a plurality of metal strut members interconnected by a plurality of hinge regions, each of the plurality of strut members having an intermediate region between adjacent hinge regions, the intermediate region being subject to relatively lower stress or strain forces than the hinge regions;

a metal covering layer disposed over at least some of the plurality of strut members and covering the intermediate region of the strut members, the covering layer having an inverted generally U-shape, such that the covering layer and the intermediate region of each strut member defines an internal cavity therebetween;

a plurality of openings formed in and passing through the covering layer and communicating between the internal cavity and external the covering layer;

and at least one bioactive agent disposed in the each internal cavity, the at least one bioactive agent capable of being released from within the at least one internal cavity through the at least one of a plurality of openings.

The Examiner rejected the claims as follows:

1. Claims 5-10, 15, 16, and 19-21 under 35 U.S.C. § 102(e) as anticipated by Brown (U.S. Patent 6,071,305, Jun. 6, 2000).

2. Claims 5-10 and 15-18 under 35 U.S.C. § 102(e) as anticipated by Dang (U.S. Patent 6,758,859 B1, July 6, 2004).

3. Claims 5-10 and 15 under 35 U.S.C. § 102(e) as anticipated by Wu (U.S. Patent 6,254,632 B1, July 3, 2001).

1. ANTICIPATION BY BROWN

Appellant argues the claims subject to this rejection in four groups as follows: claims 5-7; claims 8-10; claims 15 and 16; and claims 19-21. We select claims 5, 8, 15, and 19 as representative. 37 C.F.R. § 41.37(c)(1)(vii).

The Issue with Respect to Claims 5-7

Claim 5 is directed to an endoluminal stent comprising an open-ended tubular member with a luminal surface and an abluminal surface, an internal cavity within the tubular member containing a bioactive agent, and openings communicating between the cavity and the luminal and/or abluminal surfaces. There is no dispute that Brown discloses at least one embodiment, a helical stent as shown in Figures 1, 2, and 3, that meets these particular limitations of claim 5.

However, Appellant contends that the internal cavity of Brown's helical stent is not "***substantially isolated from stress or strain forces*** on the endoluminal stent during delivery," as further required by claim 5 (App. Br. 10).

The Examiner's position is that the internal cavity in Brown's helical stent is isolated from stress and strain during delivery of the stent because

"no stress/strain is applied until expansion, which occurs *after* delivery" (Ans. 10).

Thus, the issue raised by this rejection with respect to claim 5 is: Has Appellant established that the Examiner erred in concluding that the cavity in Brown's helical endoluminal stent is substantially isolated from stress and strain during delivery of the stent?

Findings of Fact

FF1 Appellant invented a "generally tubular" endoluminal stent "having cavitated regions incorporated within the material of the . . . [stent] with micropores that communicate a bioactive agent from the cavity to an area external the device" (Spec. 1: 15-17 and 26).

FF2 Claim 5 requires a stent made up of a tubular member having a central lumen where at least one internal cavity is located in a portion of the tubular member that is substantially isolated from stress or strain during delivery of the stent.

FF3 The Specification teaches that "all stents have certain structural regions that are subject to higher stress and strain conditions than other structural regions" because "stents necessarily are delivered in a reduced diametric state and are expanded or allowed to expand *in vivo* to an enlarged diametric state" so that they can serve as structural supports once in place (Spec. 5: 6-9). In other words, stents are initially biased toward a reduced state, and forced into an expanded state once in place, or they are initially biased toward an expanded state, but forced into a reduced state for delivery, and allowed to expand once in place.

FF4 According to the Specification, "it may be advantageous to position the internal cavities that retain the bioactive agents in structural regions of the stent that are subjected to relatively lower stress and strain during endoluminal delivery and deployment. Alternatively, where delivery of a bolus of a bioactive agent is desired, internal cavities may be positioned in regions that undergo large deformation during delivery and deployment thereby forcing the bioactive agent out of the internal cavity under the positive pressure exerted by the deformation" (Spec. 5: 9-15).

FF5 Further according to the Specification, internal cavities may "reside within regions of the device . . . that are substantially non-load bearing" (Spec. 12: 6-7). Alternatively, "regions . . . that are deformed or that are load bearing may include . . . internal cavities within their wall thickness and provide for elution of a bioactive agent retained within the internal cavity positioned at the load bearing region under the influence of a positive motivating pressure exerted on the bioactive agent by deformation or load stress transferred by the device geometry to the internal cavity and to the bioactive agent" (Spec. 12: 10-15).

FF6 The Specification does not explicitly identify regions that are "substantially isolated from stress or strain forces on the endoluminal stent during delivery" (as required by claim 5), but it can be inferred from the passages quoted in FF4 and FF5 that regions of the stent that undergo "large deformation" during delivery and deployment, and/or load bearing regions, are subject to higher stress and strain conditions than other structural regions, while regions that do not undergo "large deformation," or are non-load bearing, are regions that are subject to lower stress and strain.

FF7 The Specification teaches that "hinge regions . . . are load bearing regions of the stent" (Spec. 12: 8-9), thus, hinge regions are regions that are subject to higher stress and strain during delivery and deployment.

FF8 An example of a stent with internal cavities located in regions substantially isolated from stress and strain is depicted in Figure 11 of the Specification, reproduced immediately below:

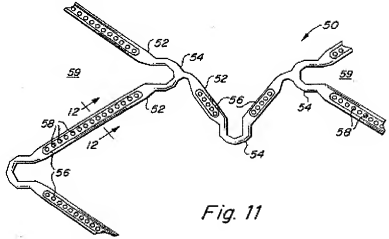

Fig. 11

Figure 11 shows a portion of an expandable stent in which "the plurality of hinge regions 54 are devoid of internal cavities 56 because they are load bearing regions of the stent" (Spec. 12: 8-9).

FF9 Brown describes a drug delivery stent **11**, an example of which is illustrated in Figures 1 and 2, reproduced immediately below:

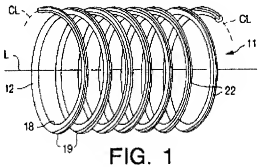

FIG. 1

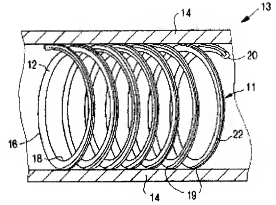

FIG. 2

Figure 1 is a perspective view of a stent **11** "formed from an elongated or tubular member **12** . . . [which] is in the shape of a coil or helix, and is expanded within a body lumen" after delivery (Brown, col. 5, ll. 39-42). Figure **2** is a cross-sectional view of a body lumen and a perspective view of stent **11** in place in the lumen (Brown, col. 3, ll. 63-65).

FF10 "The tubular or elongated member **12** of [Brown's] directional drug delivery stent **11** . . . is formed with an interior or cavity **20**, which . . . is a concave groove within the interior of the elongated member **12**" (Brown, col. 5, ll. 45-50). "[C]avity **20** contain[s] a biologically active agent for directional application" (Brown, col. 4, ll. 62-63).

FF11 "Although the cavity **20** illustrated in [Brown's] Fig. **2** is a concave groove, the interior may be other configurations and need not extend the entire length of the elongated or tubular member **12**" (Brown, col. 5, ll. 51-54). In addition, "[a]lthough the slit shaped opening **22** is illustrated, any number of fluid opening configurations may be fashioned. For example, a series or plurality of holes, grooves, small indentations, and intermittent recessions could all be fluid openings and delivery means for

directionally delivering the biologically active agent" (Brown, col. 6, ll. 13-17).

FF12 An embodiment of Brown's helical stent with the cavity on the luminal surface of the elongated, tubular member is shown in Figure **3**, reproduced immediately below:

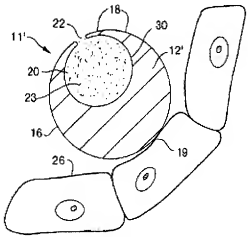

FIG. 3

Brown's Figure **3** is a "cross-sectional view of the elongated member **12´** of the stent **11´"** (Brown, col. 8, ll. 5-6), in which cavity **20** and opening **22** extend along the luminal surface of elongated, tubular member **12´**. That is, both the cavity and the opening are on the inside surface of the stent.

FF13 Brown's helical stent "has an initial diameter at which it is inserted into a body lumen, and an expanded final diameter" once in place (Brown, col. 7, ll. 26-28).

Analysis and Conclusion of Law, Claims 5-7

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

According to the Examiner, the cavity in Brown's helical stent "resid[es] within the wall thickness in portions of the tubular member that are substantially isolated from stress or strain forces . . . during delivery" (Ans. 4), at least in part because Brown's stent is delivered in an un-expanded state, and is subjected to minimal stress and strain until expansion, "which occurs *after* delivery" (Ans. 10).

Appellant contends that "Brown discloses a helical coil stent structure, where all the regions would undergo substantial stress and strain forces during delivery and deployment . . . Consequently, Brown does not contain the element recited in Claim 5 of an internal cavity substantially isolated from stress or strain forces" (App. Br. 11).

Appellant's argument is not persuasive. The Specification identifies hinge regions as regions of relatively high stress and strain during delivery and deployment (FF5, 6, 7). Brown's helical stent has no hinge regions (FF9). Nevertheless, even if we accept for the sake of argument that "all of the regions" in Brown's helical stent would undergo stress and strain at some point during delivery and deployment, the Specification distinguishes between delivery and deployment (FF3), and claim 5 merely requires isolation from stress and strain during *delivery* (FF2). Brown's stent is delivered to a location in a vessel in an initial, unexpanded state, and is expanded to its final diameter (i.e., deployed) *after* delivery (FF13).

Appellant has not established that Brown's helical stent is either load-bearing or deformed during delivery, as opposed to deployment (i.e., expansion). Therefore, Appellant has not shown that the Examiner erred in

concluding that "minimal stress/strain" is placed on the cavity of Brown's stent during delivery (Ans. 10).

The Issue with Respect to Claims 8-10

Claim 8 is directed to an endoluminal stent comprising a cylindrical member comprised of a plurality of interconnected structural elements defining walls, with a plurality of discontinuous interior cavities disposed within at least some of the structural elements.

The Examiner asserts that at least one of Brown's embodiments, an expandable "tube-type" stent as shown in Figure **18**, meets all of the limitations of claim 8, including the requirement for a plurality of discontinuous interior cavities.

Appellant contends that "Brown does not disclose 'a plurality of discontinuous interior cavities disposed completely within at least some of the plurality of structural elements', as recited in Claim 8" (App. Br. 11).

Thus, the issue raised by this rejection with respect to claim 8 is: Has Appellant established that the Examiner erred in concluding that the cavities in Brown's tube-type stent are discontinuous?

Additional Findings of Fact

FF14 Claim 8 is directed to an endoluminal stent comprising a cylindrical member comprised of a plurality of interconnected structural elements defining walls of the cylindrical member, with "a plurality of discontinuous interior cavities disposed completely within at least some of the plurality of structural elements," a plurality of openings communicating between each of the cavities and the outside of the stent, and at least one bioactive agent disposed within the cavities.

FF15 According to the Specification, "both the plurality of internal cavities 12 and the plurality of pores [i.e., openings] 14 may be positioned to be discontinuous and in different circumferential or different longitudinal regions of the tubular body 20" (Spec. 7: 21-23). In addition, "[w]ithin a single one of the plurality of interconnected structural elements 21, the internal cavities 12 may be separated by a separation member 25, which completely subtends the internal cavity 12, divid[ing] it into discrete discontinuous internal cavities 12" (Spec. 7: 23-26).

FF16 Brown describes a number of stent configurations other than the helical stent discussed above, such as "expandable tube stents, roving wire stents, and wire mesh stents. Thus the elongated member **12** may be the filaments or fibers which form a mesh stent" (Brown, col. 7, ll. 37-39).

FF17 Brown's Figures 17 and 18 show an expandable tube-type stent before and after expansion, respectively. Figures 17 and 18 are reproduced immediately below:

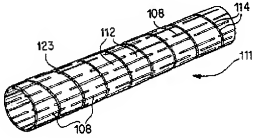

FIG. 17

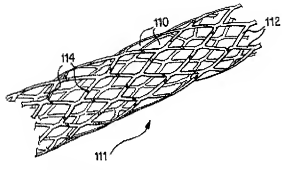

FIG. 18

Figure 17 "illustrates an example of the aforementioned expandable tube-type stent **111** . . . [Figure 18] illustrates the stent . . . in an expanded state" (Brown, col. 11, ll. 63-64).

FF18 Brown's "tube-type stent **111** is manufactured by cutting an elongated tubular member into tubular sections" (Brown, col. 12, ll. 1-2). Then, "[a] recessed active agent receiving . . . groove **120** is formed in the exterior surface **104** of the tube **102**. The groove **120** . . . is preferably a continuous helical or coiling groove extending around the tube **102** . . . the groove **120** need not be continuous" (Brown, col. 12, ll. 14-20). "Once the . . . groove **120** has been filled with active agent **123** . . . a plurality of . . . slots **108** are formed in the tube **102** . . . and extend completely through the tubular member . . . wall thickness" (Brown, col. 12, ll. 61-67).

FF19 Brown teaches that "one function of the slots is to permit the stent **111** to be expanded" (Brown, col. 13, ll. 9-10). "Because the preferred slots **108** extend longitudinally along the tube **102** and the . . . groove **120** extends helically around the tubular member, *the slots intersect the groove to define a plurality of spaced apart groove portions* **114**, each containing active agent" (Brown, col. 13, ll. 14-19 (emphasis added)). In other words, "[w]hen the tube is expanded, the tubular material between the slots **108**

forms the angled fibers or elongated members **112**, and the slots **108** form the interstitial openings **110** . . . . At least some of the elongated members **112** contain groove portions **114** or cavities in which the active agent is located" (Brown, col. 13, ll. 23-29).

FF20 Thus, Brown describes a stent with spaced apart, i.e., discontinuous, interior cavities.

Analysis and Conclusion of Law, Claims 8-10

Appellant contends that "Brown's 'plurality of cavities' in Fig. 18 does not make them discontinuous. For Claim 8, a discontinuous cavity is a *single* cavity marked by a break or interruption" (Reply Br. 9). Appellant concedes that Brown "disclose[s] a number of cavities per filament," but contends that "'Discontinuous' modifies cavity, thereby making 'discontinuous interior cavities' requiring that the cavity itself . . . be discontinuous, not the plurality of cavities to be discontinuous" (*id.*).

Appellant's argument is not persuasive. According to the Specification, the cavities may be "discontinuous" in two ways: (1) they are "positioned to be discontinuous and in different circumferential or different longitudinal regions of the tubular body" (FF15), or (2), "[w]ithin a single one of the plurality of interconnected structural elements 21, the internal cavities 12 may be separated by a separation member 25 . . . [dividing the cavities] into discrete discontinuous internal cavities 12" (FF15).

Claim 8 is not limited to the second embodiment described in the Specification where a single cavity is divided into discrete, discontinuous portions (FF14). Claim 8 merely requires "a plurality of discontinuous interior cavities disposed completely within at least some of the plurality of

structural elements" (FF14). Brown describes spaced apart grooves (i.e., cavities) disposed within different regions of the stent (FF19, 20), thereby meeting the requirement of claim 8 for discontinuous interior cavities.

Appellant has not established that the Examiner erred in concluding that the cavities in Brown's tube-type stent are discontinuous.

The Issue with Respect to Claims 15 and 16

Claim 15 is directed to a radially expandable, cylindrical endoluminal stent comprising a plurality of struts interconnected at a plurality of hinge regions. At least some of the struts are comprised of a first region "having a first wall thickness" in proximity to one of the plurality of hinge regions, and a second region "having a second wall thickness" substantially isolated from each of the plurality of hinge regions, with at least one void space formed entirely within the second wall thickness of the second region (claim 15).

Appellant contends that Brown only discloses stents with struts comprising a single wall thickness, and that Brown does not disclose "'a second region being substantially isolated from each of the plurality of hinge regions; [with] at least one void space formed entirely within the second wall thickness of the second region'" (App. Br. 13), and therefore fails to meet all the limitations of claim 15.

The Examiner asserts that claim 15 does not require the first and second thicknesses to be "two different thicknesses" (Ans. 11), nor does the claim "*exclude* . . . [void spaces] from being on the first region of the stent" (*id.*).

The issue raised by this rejection with respect to claim 15 is: Has the Examiner established that Brown anticipates the invention of claim 15 based on the broadest reasonable interpretation of the claim consistent with Appellant's Specification?

Additional Findings of Fact

FF21 The Examiner finds that Brown's expandable "tube-type" stent, shown in Figure **18**, meets all the limitations of claims 15 and 16, including the requirement for struts comprising first and second wall thicknesses, and the requirement for at least one void space formed entirely within the second wall thickness of the second region, where the second region is substantially isolated from each of the hinge regions (Ans. 5).

FF22 Appellant's claim 17, which depends from claim 15 and is not subject to this rejection, stipulates that "the second wall thickness is greater than the first wall thickness," further limiting the first and second wall thicknesses to two different wall thicknesses. Thus, claim 15 does not require the first and second wall thicknesses to be two different wall thicknesses.

FF23 According to Appellant's Specification, cavities may be located in both load bearing regions (e.g., hinge regions) and non-load bearing regions (e.g., regions isolated from hinge regions), in order to achieve the desired rate and timing of elution of the active agent(s) (Spec. 12: 18).

FF24 Claim 15 requires "at least one void space formed entirely within the second wall thickness of the second region" which is "substantially isolated from each of the plurality of hinge regions," but the claim uses the open transitional term "comprising," and is therefore not

limited to a stent with voids located *exclusively* in regions isolated from the hinge regions.

FF25 The expandable tube-type stent shown in Brown's Figures 17 and 18 (reproduced above) has "[a] recessed active agent receiving portion or groove **120** . . . formed in the exterior surface of the tube **102**" (Brown, col. 12, ll. 14-15). "Once the recessed active agent receiving portion or groove **120** has been filled with active agent **123** . . . a plurality of perforations, slits, or slots **108** are formed in the exterior surface **104** of the tube **102**, and extend completely through the tubular member thickness" (Brown, col. 12, ll. 61-67). Slots **108** "intersect the groove to define a plurality of spaced apart groove portions **114**, each containing the active agent" (Brown, col. 13, ll. 17-19).

FF26 Figure 18 (reproduced above) shows several spaced apart groove portions or recessed active agent receiving portions **114** that are formed entirely within regions that are substantially isolated from the hinge regions.

Analysis and Conclusion of Law, Claims 15 and 16

"[D]uring examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification." *In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000).

> [T]he PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification.

In re Morris, 127 F.3d 1048, 1054 (Fed. Cir. 1997). However, the claims are not to be confined to the embodiments found in the Specification, and it is improper to import limitations from the Specification into the claims. *In re Trans Texas Holdings Corp.*, 498 F.3d 1290, 1299 (Fed. Cir. 2007).

Appellant contends that Brown does not disclose "two different wall thicknesses" as required by claim 15 (App. Br. 13).

This argument is not persuasive. Claim 15 does not require that the first and second wall thicknesses are different (as opposed to narrower dependent claim 17, which does) (FF22).

Appellant contends that "Brown's Fig. 18 . . . clearly shows groove portions 114 [that] intersect with or are immediately adjacent to . . . hinge regions of the stent struts 112 . . . Thus, it cannot be said that the groove portions 114 are ***substantially isolated from each*** [and every] of the plurality of hinge regions, as claimed" (App. Br. 13, 14).

This argument is not persuasive. Claim 15 merely requires "at least one void space formed entirely within the second wall thickness of the second region" which is "substantially isolated from each of the plurality of hinge regions," and the open language of the claim does not preclude voids located in the hinge regions as well (FF24) Moreover, this interpretation of the claim is consistent with the Specification, which teaches that cavities (i.e. void spaces) may be located in both load bearing regions (e.g. hinge regions), as well as non-load bearing regions, depending on the desired elution profile (FF23).

Finally, Appellant argues that groove space 114 "is not a 'void space formed entirely within' a second wall thickness . . . [because] the groove

portions 114 open not only at their upper opening, but the end openings defined in the stent struts become exposed to the exterior of the wall thickness of elongated members 112 . . . [and] the open surface of the groove 123 changes as the stent is radially expanded" (App. Br. 14).

This argument is not persuasive. Brown's grooves are located in the walls of the struts. Appellant has not identified anything in the Specification which supports his restrictive definition of "a void space entirely within" the wall thickness.

The Examiner has established that Brown anticipates the stent of claim 15, based on a reasonable interpretation of the claim consistent with the Appellant's Specification.

The Issue with Respect to Claims 19-21

Claim 19 is directed in part to a drug eluting stent comprising a plurality of metal strut members interconnected by a plurality of hinge regions. The claim requires a generally U-shaped metal covering layer with a plurality of openings formed in it, disposed over the intermediate regions between adjacent hinges of at least some of the struts, defining an internal cavity therebetween.

The Examiner asserts that the requirement for a U-shaped metal covering is met by "portion 19" of Brown's drug eluting stent (Ans. 6).

Appellant contends, at least in part, that "portion 19 is a portion of the circumference of the elongated member . . . [and] is not a layer as to anticipate Claim 19's metal covering layer" (App. Br. 16).

The issue raised by this rejection with respect to claim 19 is: Has the Examiner provided an adequate factual basis to support her conclusion that Brown discloses a stent with a U-shaped metal covering?

Additional Findings of Fact

FF27 The Examiner asserts that the required U-shaped "metal covering layer may be considered to be [the] top layer of the stent 19, . . . [as shown in] fig. 4, 6 for example" (Ans. 6).

FF28 Brown's Figure 4 is reproduced immediately below:

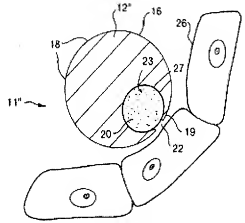

FIG. 4

Figure 4 is a cross-sectional view of the elongated member **12"** of a stent **11"** which "directionally delivers the biologically active agent **23** from the cavity **20** and through the slit opening **22**, which is located at the support portion **19** of the outer surface **16**, such that the biologically active agent is delivered to the body lumen wall **26**" (Brown, col. 8, ll. 55-60).

FF29 Elongated member **12"** can form the struts of a mesh stent (FF21), however, support portion **19** is an integral part of elongated member **12"**, and is not a U-shaped metal layer covering portion of the elongated member/strut **12"**.

Analysis and conclusion of Law, Claims 19-21

> The Patent Office has the initial duty of supplying the factual basis for its rejection. It may not, because *it* may *doubt* that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in its factual basis. To the extent the Patent Office rulings *are* so supported, there is no basis for resolving doubts against their correctness. Likewise, we may not resolve doubts in favor of the Patent Office determination when there are deficiencies in the record as to the necessary factual bases supporting its legal conclusion . . .

In re Warner, 379 F.2d 1011, 1017 (CCPA 1967) (emphasis in original). *Warner* concerned the factual basis of an obviousness rejection, but its central premise is equally appropriate here.

Even if we accept, for the sake of argument, that Brown's support portion **19**, which is an integral part of elongated member/strut **12"** (FF29), is a "covering layer" forming a cavity between the strut and support portion **19**, the Examiner has not pointed to anything in Brown which shows that it is U-shaped.

Thus, the Examiner has not provided the factual basis necessary to support her conclusion that Brown discloses a stent with a U-shaped metal covering.

Decision with Respect to Anticipation by Brown

We affirm the rejection of the claims under 35 U.S.C. § 102(e) as anticipated by Brown with respect to claims 5-10, 15, and 16, but reverse the rejection with respect to claims 19-21.

2. ANTICIPATION BY DANG

The Examiner rejected claims 5-10 and 15-18 under 35 U.S.C. § 102(e) as anticipated by Dang.

The Issue

The Examiner's position is that Dang describes an endoluminal stent comprising a tubular member that meets all of the limitations of claims 5-10 and 15-18, including the requirement for "a plurality of openings communicating between the at least one internal cavity and at least one of the luminal surface, abluminal surface, proximal end or distal end of the tubular member" (claim 5); the requirement for "a plurality of openings communicating between each of the . . . interior cavities and external the stent" (claim 8); and the requirement for "a plurality of pores communicating between the at least one void space [formed entirely within the wall of the stent] . . . and external the endoluminal stent" (claim 15).

Appellant contends in part that Dang does not teach or disclose a "***plurality of openings***" or a "***plurality of pores***" communicating between any single internal cavity or void space in the wall of the stent and the exterior of the stent (App. Br. 21, 23), as required by all the claims subject to this rejection. In other words, Appellant contends that Dang discloses only a "***single opening***" per cavity or void space (*id.* at 21).

Thus, the issue raised by this rejection with respect to claims 5-10 and 15-18 is: Has the Examiner provided an adequate factual basis to support her conclusion that Dang discloses a stent with a plurality of openings or pores communicating between an internal cavity or void and the surface of the stent?

Findings of Fact

FF30 All of the claims subject to rejection over Dang require a plurality of openings or pores communicating between a single internal cavity or void, residing or disposed within the wall thickness or structural elements of the stent, and the exterior of the stent. That is, all of the claims require more than one opening or pore per cavity or void. Moreover, the luminal surface of the stent is not a cavity or void residing or disposed within a wall thickness or structural element of the stent.

FF31 Dang describes a cylindrical or tubular expandable "prosthesis, one example of which includes a stent . . . The outer surface of the prosthesis is capable of contacting an inner lumen surface of a passageway. In addition, the body structure of the prosthesis has one or more elements having a width and a thickness. The width of the element(s) is variable from a nominal or conventional width to an increased width" (Dang, col. 2, ll. 41-51).

FF32 Dang's "variable width prosthesis includes one or more depots formed on the elements of the prosthesis. The depots have an open end, a closed end, a diameter and a depth that is less than the thickness of the body structure of the prosthesis. In general, the depots are formed at the increased width sections of the elements" (Dang, col. 2, ll. 52-58).

FF33 "The depots **30** are formed to carry . . . therapeutic substances" (Dang, col. 5, ll. 10-11), and the depth, diameter, and quantity of the depots, as well as their location on the elements **22** of the stent, varies according to intended usage and application (Dang, col. 6, ll. 24-27; col. 8, ll. 29-30).

FF 34 Dang's Figures **5***a* and **5***b*, reproduced immediately below, show cross-sectional and top views of "a plurality of depots on a surface portion" of a stent (Dang, col. 3, ll. 20-23):

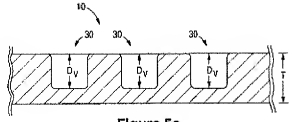

Figure 5a

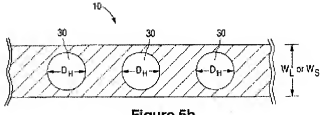

Figure 5b

Figures **5***a* and **5***b* illustrate cross-sectional and top views of individual depots **30** for therapeutic substances.

FF35 While Dang's stent has a plurality of depots, and "depot configurations . . . can include . . . tear-drop shaped, cubic shaped, spherically shaped, and other configurations and shapes" (Dang, col. 6, ll. 60-63), none of the depots described by Dang has more than one opening per depot.

Analysis and Conclusion of Law

All of the claims subject to this rejection require a plurality of openings or pores per cavity or void (FF30), not merely a plurality of openings or pores in the stent as a whole.

The Examiner asserts that Dang describes a stent with "a plurality of openings (open end is considered an 'opening' . . . [and] the cavities may be

any shape, including shapes such as tear drop, wherein the opening is smaller that the cavity . . .) communicating between the at least one internal cavity (30) and at least one of the luminal surface, abluminal surface, proximal end, or distal end of the tubular member (fig. 5a)" (Ans. 7).

We agree with Appellant that "no single depot 30 disclosed in the Dang reference contains a 'plurality of openings', i.e., more than one opening . . . [and] [a] tear drop opening still only contains a ***single opening***" (App. Br. 21).

Thus, the Examiner has not provided an adequate factual basis to support her conclusion that Dang discloses a stent with a plurality of openings or pores communicating between an internal cavity or void and an exterior surface of the stent.

Decision

We reverse the rejection of claims 5-10 and 15-18 under 35 U.S.C. § 102(e) as anticipated by Dang.

3. ANTICIPATION BY WU

The Examiner rejected claims 5-10 and 15 under 35 U.S.C. § 102(e) as anticipated by Wu.

The Issues

Appellant contends, among other things, that "Wu does not disclose 'a plurality of openings communicating between the at least one internal cavity and at least one of the luminal surface'" as required by claims 5-7 (App. Br. 27), or "a plurality of discontinuous interior cavities disposed completely within at least some of the plurality of structural elements" (*id.* at 28) with "a plurality of openings communicating with an internal cavity and external the

stent" as required by claims 8-10 (*id.* at 29); or "a 'void space formed entirely within the second wall thickness' of a strut region" as required by claim 15 (*id.*).

The Examiner's position is that "Wu discloses a stent . . . comprising a structural member (104, 102) and cover member (420) and a cavity (area occupied by agent 410 . . .) therebetween, and a plurality of openings (openings in porous polymer cover 420) passing through the cover member" (Ans. 9).

The issues raised by this rejection are: Has the Examiner provided an adequate factual basis to support her conclusion that Wu discloses a stent with a plurality of openings or pores communicating between an internal cavity and the surface of the stent, and that Wu describes a stent with cavities or void spaces formed entirely within the structural elements or struts of the stent, with a plurality of openings communicating between the cavities or void spaces and the exterior of the stent?

Additional Findings of Fact

FF36 Wu describes "protruding structures . . . [on] the surface of a stent . . . [which] can be used with covered stents . . . to engage and secure the cover, . . . to keep glue in place on the stent when attaching the covering. The protruding structures can also be used to deliver therapeutic substances from the stent directly to the lumen wall" (Wu, col. 2, ll. 53-62).

FF37 "An exemplary protruding structure includes a depression region having a bottom surface that is fully or partially surrounded by a protruding lip . . . [that] is higher than the bottom surface relative to the surface of the stent" (Wu, col. 2, l. 64 to col. 3, l. 2).

FF38 Wu's Figure **2**B is reproduced immediately below:

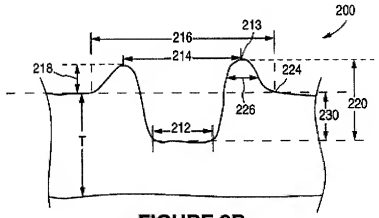

FIGURE 2B

Figure **2**B "is a cross-sectional side view of a portion of a stent strut with a crater that has a bottom surface recessed beneath the stent surface" (Wu, col. 3, ll. 46-48).

FF39 Wu's Figure **4**A is reproduced immediately below:

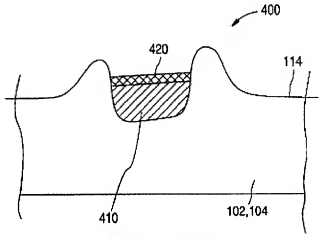

FIGURE 4A

Figure **4**A is a cross-sectional side view of a "protruding structure[ ] that contain[s] a therapeutic substance . . . covered by a polymeric layer" (Wu, col. 3, ll. 63-65).

FF40 The Examiner describes polymeric layer **420** as "porous" (Ans. 9), but does not point to anything in Wu which indicates that the polymer actually is porous. Wu merely describes the "[p]olymeric materials that can be used for layer **420**, **430** . . . [as] either bioabsorbable or biostable" polymers which "are gradually absorbed or eliminated from the body by hydrolysis, metabolic process, bulk or surface erosion" (Wu, col. 6, ll. 37-43).

FF41 The Examiner's assertion that Wu's polymer layer **420** meets the claims' requirement for a plurality of openings per cavity or void space is not supported by Wu's description of the polymer layer.

Analysis and Conclusion of Law

While Wu's stent has a plurality of cratered structures, the structures, including the craters, protrude at least partially from the surface of the stent (FF 36-39), thus none of the craters (i.e., cavities or voids) is "disposed completely within" or "formed entirely within" a structural element or strut (as required by claims 8-10 and 15). Moreover, none of the protruding structures has more than one opening per crater (as required by claims 5-10 and 15) (FF40, 41).

The Examiner has not provided an adequate factual basis to support her conclusion that Wu discloses a stent with a plurality of openings or pores communicating between an internal cavity and the surface of the stent as required by claims 5-7, or that Wu describes a stent with cavities or void spaces formed entirely within the structural elements or struts of the stent (as required by claims 8-10 and 15), with a plurality of openings communicating

between the cavities or void spaces and the exterior of the stent (as required by claims 5-10 and 15).

Decision

We reverse the rejection of claims 5-10 and 15 under 35 U.S.C. § 102(e) as anticipated by Wu.

SUMMARY

The rejection of claims 5-10, 15, 16, and 19-21 under 35 U.S.C. § 102(e) as anticipated by Brown is AFFIRMED with respect to claims 5-10, 15, and 16, but REVERSED with respect to claims 19-21.

The rejection of claims 5-10 and 15-18 under 35 U.S.C. § 102(e) as anticipated by Dang is REVERSED.

The rejection of claims 5-10 and 15 under 35 U.S.C. § 102(e) as anticipated by Wu is REVERSED.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED-IN-PART

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,695	09/26/2003	Christopher T. Boyle	6006-107	9286

7590 03/31/2009

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EXAMINER	
PRONE, CHRISTOPHER D	
ART UNIT	PAPER NUMBER
3738	
MAIL DATE	DELIVERY MODE
03/31/2009	PAPER

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6006-018
6006-070

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1) REQUEST FOR REHEARING
2) NOTICE OF APPEAL
3) RCE/AMENDMENT

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte CHRISTOPHER T. BOYLE, DENES MARTON, and CHRISTOPHER E. BANAS

Appeal 2008-5417[1]
Application 10/672,695
Technology Center 3700

Decided: March 31, 2009[2]

Before TONI R. SCHEINER, ERIC GRIMES, and LORA M. GREEN, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION ON APPEAL

---

[1] The real party in interest is Advanced Bio Prosthetic Surfaces, L.L.C.

[2] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 1-6, 8-12, 15, 18-24, 26, 27, 29-31, 34, and 35. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

"[T]he present invention provides an implantable graft that includes a microporous thin film covering comprised of a metallic . . . material and an underlying structural support made of a metallic . . . material" (Spec. 3: 22-24). "The microporous thin film covering is physically attached to the underlying structural support, preferably by welding, suturing, or other commonly known methods of attachment at particular interfacial points" (*id.* at 3: 28-30). "The underlying structural support, without the microporous thin film covering, is similar to implantable devices known as . . . 'stents'" (*id.* at 4: 5-6).

Claims 1, 18, and 29 are representative of the subject matter on appeal:

1. An implantable endoluminal graft, comprising:
(a) a microporous metal thin film covering having a pattern of microporous openings passing therethrough;
(b) a metal structural support element having at least one affixation member, a pattern of openings passing through the metal structural support element and underlying the microporous metal thin film covering comprised of a metallic material; and
(c) wherein the metal structural support element is attached to the microporous metal thin film covering only at the at least one affixation member.

18. An implantable endoluminal graft, comprising:

(a) a microporous metal thin film covering comprised of a shape memory alloy having an austenite phase transition start temperature greater than 37° C; and

(b) a structural support element underlying the microporous covering comprised of at least a pair of cylindrical elements and interconnecting members joining adjacent cylindrical elements, the structural support element further comprised of a shape memory alloy having an austenite phase transition start temperature less than 0° C;

(c) the structural support element being attached to the microporous metal thin film covering at at least one point of attachment between the microporous metal thin film covering and the structural support element.

29. An implantable endoluminal graft, comprising:

(a) a microporous metal thin film covering comprised of nitinol; and

(b) a structural support element underlying the microporous covering comprised of at least a pair of undulating cylindrical elements having a plurality of peaks and valleys and interconnecting members joining adjacent cylindrical elements at either the peaks or the valleys and having at least one projection extending longitudinally from a terminal cylindrical element, the structural support element being comprised of nitinol,

(c) the structural support element being joined to the microporous metal thin film covering at the at least one projection.

The Examiner relies on the following evidence:

Wright et al.	US 6,585,764 B2	Jul. 1, 2003
Burmeister et al.	CA 2 512 311 A1	Nov. 30, 1995

The Examiner rejected claims 1-6, 8-12, 15, 18-24, 26, 27, 29-31, 34, and 35 under 35 U.S.C. § 103(a) as unpatentable over Burmeister and Wright.

We affirm-in-part.

THE ISSUES

With respect to claim 1 and its dependent claims, the issue raised by this appeal is whether the Examiner has established that an implantable endoluminal graft comprising a microporous metal thin film covering, with microporous openings passing therethrough, attached to an underlying metal structural support through an affixation member would have been obvious over the combined teachings of Burmeister and Wright.

With respect to claim 18 and its dependent claims, the issue raised by this appeal is whether the Examiner has established that an implantable endoluminal graft comprising a microporous metal thin film covering attached to an underlying metal structural support through at least one point of attachment would have been obvious over the combined teachings of Burmeister and Wright.

Finally, with respect to claim 29 and its dependent claims, the issue raised by this appeal is whether the Examiner has established that an implantable endoluminal graft comprising a microporous metal thin film covering attached to an underlying metal structural support through at least one projection would have been obvious over the combined teachings of Burmeister and Wright.

FINDINGS OF FACT

The Invention

FF1 Independent claim 1 is directed, in pertinent part, to an implantable endoluminal graft comprising a microporous metal thin film covering having "microporous openings passing therethrough," and an underlying metal structural support element "having at least one affixation

member," wherein the structural support element is attached to the microporous covering "only at the at least one affixation member."

FF2 Independent claim 18 is directed, in pertinent part, to an implantable endoluminal graft comprising a microporous metal thin film covering and a structural support element, wherein there is "at least one point of attachment" between the microporous covering and the structural support element. Claim 18 does not recite that the microporous metal thin film has "microporous openings passing therethrough."

FF3 Independent claim 29 is directed, in pertinent part, to an implantable endoluminal graft comprising a microporous metal thin film covering and an underlying structural support element "having at least one projection extending longitudinally from a terminal cylindrical element," "the structural support element being joined to the microporous . . . covering at the at least one projection." Claim 29 does not recite that the microporous metal thin film has "microporous openings passing therethrough."

FF4 "A principal . . . example of the present invention . . . [is an] endovascular stent[ ]" (Spec. 1: 29-30), and the underlying structural support element of the graft/stent "provides the necessary structural component to support an endoluminal wall" (*id.* at 3: 18).

FF5 The Specification describes an "alternative embodiment" in which the microporous metal thin film covering overlying the structural support of the stent/graft has a "plurality of openings" (Spec. 21: 23), and the openings "can have a varying size . . . so that cellular migration occurs

thorough each opening" (*id.* at 21: 20-22), "permitting transmural endothelialization"[3] (*id.* at 21: 28) of the graft.

Burmeister

FF6 Burmeister describes a stent "comprised of at least one . . . portion which exhibits a tendency to self-expand the device to an expanded size and at least one other . . . portion which is deformable so as to allow an external force . . . to further expand it to a final, larger desired expanded size" (Burmeister 3: 5-10). "[T]he portions may be discrete or merely different phases of an alloy" (*id.* at 3: 18-19).

FF7 Figure 3 of Burmeister "is an end view of a layered stent having two discrete components" (Burmeister 4: 6-7). Figure 3 is reproduced below:

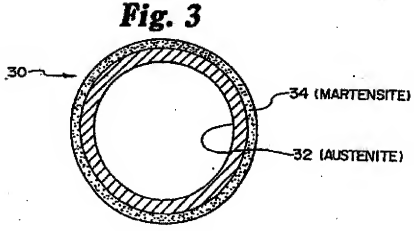


Figure 3 depicts a layered stent with "martensitic and austenitic phase characteristics of shape memory alloy(s) in the two discrete components 32

[3] Transmural: an adjective defined as "passing or administered through an anatomical wall; *also* "involving the whole thickness of a wall" (http://dictionary.reference.com/browse/transmural (accessed: February 13, 2009)).

and 34" (Burmeister 9: 23-24). "[T]he austenitic portion [may be made] with any standard metallurgical technique and . . . the martensitic portion [may be vapor deposited] on its surface. Other manufacturing techniques such as diffusion bonding, welding, ion beam deposition, and various others will be apparent" (*id.* at 9: 3-7).

FF8 The Examiner finds that Burmeister's component 32 is a structural support element, and component 34 is a thin film covering (Ans. 4), and that "the two layers . . . are completely bonded together throughout their surface areas" and "[t]his intersection of the two members is considered to be the affixation member" or "point of attachment" required by the claims (*id.* at 6).

FF9 The Examiner finds that "Burmeister does not disclose that the thin film covering comprises a microporous surface" (Ans. 4).

FF10 Wright describes a stent "whose body has been modified to contain micropores or channels" that act as reservoirs for a therapeutic agent which will be delivered to the vessel wall (i.e., to the outside, or abluminal side of the stent) (Wright, col. 6, ll. 49-50; col. 3, ll. 51-55).

FF11 Wright's Figures 1a and 1b, reproduced below, show top and section views of a stent containing reservoirs:

FIG. 1

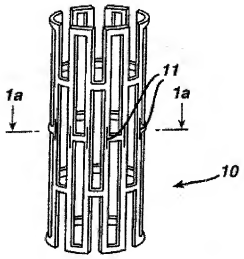
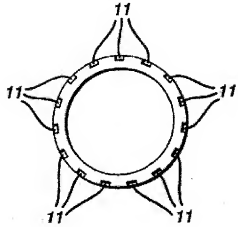


FIG. 1a



Figures 1a and 1b depict stent struts containing drug reservoirs (11).

FF12 According to the Examiner, Wright's implantable stent comprises "a microporous outer surface" (Ans. 4) which "qualif[ies] as an equivalent structure" (*id.* at 6) to the microporous metal thin film covering required by the present claims.

PRINCIPLES OF LAW

> [T]he PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification.

In re Morris, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

ANALYSIS

According to the Examiner, Burmeister's stent has "2 distinct layers clearly shown in figure 3" (Ans. 5). "[T]he outer layer 34 [is] a thin metal film and the[ ] inner layer 32 [is] a support layer" (*id.*). According to the Examiner, "the two layers of Burmeister are completely bonded together throughout their surface areas" and "[t]his intersection of the two members is considered to be the affixation member" or "point of attachment" required by the claims (*id.* at 6).

The Examiner acknowledges that "Burmeister does not disclose that the thin film covering [32] comprises a microporous surface" (Ans. 4), but concludes that it would have been obvious to "combine the microporous outer surface as taught by Wright with the implant of Burmeister in order to deliver a drug to the implant site" (*id.* at 5).

Appellants contend that "the claims on appeal require an actual element described as an 'affixation member', a 'point of attachment', or a 'projection,'" (App. Br. 12), which accomplishes "the physical joining of the microporous thin film covering and the structural support element" (*id.* at 13). Appellants contend that the "interface between a martensitic layer 34 and an austenitic layer 32" in Burmeister's bi-layered stent is merely where "the two layers of the Burmeister stent touch each other" (*id.* at 11), and "does not constitute an affixation element" (*id.* at 12).

We agree with Appellants that independent claims 1 and 29, at least, require an "actual element" (App. Br. 12), i.e., an "affixation member" or a "projection" joining the covering and the structural support element, and that this limitation is not met by Burmeister's two adjacent layers. Independent claim 18, however, does not specify any particular element joining the

covering and the support layer, but merely requires that the covering and support element are attached at "at least one point of attachment." We agree with the Examiner that Burmeister's layers are attached at "at least one point of attachment."

Nevertheless, Appellants additionally contend that the "microporous metal thin film covering" required by the claims has micropores "passing therethrough" (App. Br. 7), that is, it has "holes or openings passing through the thickness of the metal thin film covering" (*id.*). Appellants contend that "[t]he 'microporous metal thin film covering having a pattern of microporous openings passing therethrough' represents a key feature" of the invention (*id.* at 9).

Appellants acknowledge that "Wright does use the term 'micropores,'" but contend that Wright's micropores "are, in fact, reservoirs or depots, and are not actual holes passing through a thin film covering" (*id.* at 7), thus, the surface of Wright's stent "do[es] not correspond to the 'microporous metal thin film covering having a pattern of microporous openings passing therethrough' as recited in the instant claims" (*id.*). Appellants contend that "the Examiner's combination of Burmeister and Wright would not be capable of achieving effective endothelialization because such a stent would not have microporous openings that traverse the metal thin film covering . . . [and] cell migration from the abluminal surface to the luminal surface would be completely obstructed" (*id.* at 10).

Wright uses the terms "micro-pores" and "channels" in describing the drug reservoirs in his stents, but it is clear, especially from Wright's Figure 1b, that the micropores or channels do not traverse the thickness of the stent strut, but are actually wells or grooves in the strut (**FF10, 11**).

Therefore, we agree with Appellants that even if one were to combine Wright with Burmeister, the resultant stent/graft would not have "a microporous metal thin film covering having . . . microporous openings passing therethrough" as required by claim 1 (and its dependent claims 2-6, 8-12, and 15).

However, unlike claim 1, independent claims 18 and 29 do not recite that the microporous metal thin film has "microporous openings passing therethrough" (**FF2**, **FF3**), nor do they require passages permitting cellular migration from one side of the film to the other. Nor does the Specification explicitly define the term "microporous" as requiring openings that go all the way through the metal thin film. Appellants point to page 21 of the Specification in support of their contention that the claims require "openings passing therethrough," but page 21 merely describes an "alternative embodiment" that permits transmural endothelialization (**FF5**).

Appellants further contend that the Specification provides a definition through "co-pending, commonly assigned U.S. Patent Applications S.N. 10/135,316 and 10/135,626, . . . both of which are hereby expressly incorporated by reference as describing the microporous thin film covering" (Reply Br. 2 (quoting the present Specification at paragraph 10)). However, the applications refer to, but do not define, "microperforations," and all of the passages pointed to by Appellants qualify the term as "passing through the film" or "passing through the graft" (Reply Br. 2-4). Unlike present claim 1, which specifies that the microporous metal thin film has "microporous openings passing therethrough" (**FF1**), claims 18 and 29 do not include this, or similar qualifying language, and are therefore broader than claim 1(**FF2**, **FF3**).

Wright describes a stent with "micropores" (**FF10**), and the present Specification does not define the term in a way that distinguishes the "microporous metal thin film" of claims 18 and 29 from Wright's stent "whose body has been modified to contain micropores" (**FF10**). Therefore, we agree with the Examiner that Wright's implantable stent comprises "a microporous outer surface" (Ans. 4) which "qualif[ies] as an equivalent structure" (*id.* at 6) to the microporous metal thin film covering (**FF12**) required by claims 18 and 29, and their dependent claims.

In summary, claims 1-6, 8-12, and 15 require a "microporous metal thin film covering having . . . microporous openings passing therethrough," a feature neither taught nor suggested by Burmeister or Wright. In addition, claims 1-6, 8-12, 15, 29-31, 34, and 35 require an "actual element," i.e., an "affixation member" or a "projection" joining the covering and the structural support element, yet another feature neither taught nor suggested by Burmeister or Wright. Claims 18-24, 26, and 27 do not require either of these features, and we agree with the Examiner that the limitations of these claims are suggested by the combined disclosures of Burmeister and Wright.

CONCLUSIONS OF LAW

With respect to claims 1-6, 8-12, and 15, the Examiner has not established that an implantable endoluminal graft comprising a microporous metal thin film covering, with microporous openings passing therethrough, attached to an underlying metal structural support through an affixation member would have been obvious over the combined teachings of Burmeister and Wright.

With respect to claims 18-24, 26, and 27, the Examiner has established that an implantable endoluminal graft comprising a microporous

metal thin film covering attached to an underlying metal structural support through at least one point of attachment would have been obvious over the combined teachings of Burmeister and Wright.

Finally, with respect to claims 29-31, 34, and 35, the Examiner has not established that an implantable endoluminal graft comprising a microporous metal thin film covering attached to an underlying metal structural support at at least one projection would have been obvious over the combined teachings of Burmeister and Wright.

Accordingly, the rejection of the claims under 35 U.S.C. § 103(a) as unpatentable over Burmeister and Wright is REVERSED with respect to claims 1-6, 8-12, 15, 29-31, 34, and 35, but AFFIRMED with respect to claims 18-24, 26, and 27.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED-IN-PART

LP

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte CHRISTOPHER T. BOYLE

Appeal 2008-1062
Application 10/258,087
Technology Center 3700

Decided: December 22, 2008

Before TONI R. SCHEINER, ERIC GRIMES, and LORA M. GREEN, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims directed to an endoluminal stent. The claims stand rejected as anticipated. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm-in-part.

STATEMENT OF THE CASE

"[T]he present invention relates to an implantable medical device, such as an endoluminal stent . . . having cavitated regions incorporated within the material of the device with micropores that communicate a bioactive agent from the cavity to an area external the device" (Spec. 1: 13-17).

Claims 5-10 and 15-21 are pending and on appeal. Claims 1-4 and 11-14 have been canceled.

Claims 5, 8, 15, and 19 are representative of the subject matter on appeal:

5. An endoluminal stent, comprising:

a tubular member having a central lumen passing longitudinally through the tubular member and open at opposing ends of the tubular member, a luminal surface and an abluminal surface and a wall thickness defined therebetween, at least one internal cavity residing within the wall thickness in portions of the tubular member that are substantially isolated from stress or strain forces on the endoluminal stent during delivery, a plurality of openings communicating between the at least one internal cavity and at least one of the luminal surface, abluminal surface, proximal end or distal end of the tubular member, and at least one bioactive agent disposed in the at least one internal cavity.

8. An endoluminal stent, comprising:

a cylindrical member comprised of a plurality of interconnected structural elements defining walls of the cylindrical member, a plurality of discontinuous interior cavities disposed completely within at least some of the plurality of structural elements, and a plurality of openings communicating between each of the plurality of discontinuous interior cavities and external the stent, and at least one bioactive agent disposed within the plurality of discontinuous interior cavities.

15. An endoluminal stent for delivering a bioactive agent to a situs in a body, comprising:

a plurality of struts interconnected at a plurality of hinge regions forming a radially expandable cylindrical member, at least some of the plurality of struts being further comprised of a first regions having a first wall thickness and a second region having a second wall thickness, the first region being in proximity to one of the plurality of hinge regions and the second region being substantially isolated from each of the plurality of hinge regions;

at least one void space formed entirely within the second wall thickness of the second region, at least one of a plurality of pores communicating between the at least one void space and through the second wall thickness to at least one surface of the second region and external the endoluminal stent, and at least one bioactive agent retained within the void space and elutable through the at least one of a plurality of pores.

19. A drug eluting stent, comprising:

a plurality of metal strut members interconnected by a plurality of hinge regions, each of the plurality of strut members having an intermediate region between adjacent hinge regions, the intermediate region being subject to relatively lower stress or strain forces than the hinge regions;

a metal covering layer disposed over at least some of the plurality of strut members and covering the intermediate region of the strut members, the covering layer having an inverted generally U-shape, such that the covering layer and the intermediate region of each strut member defines an internal cavity therebetween;

a plurality of openings formed in and passing through the covering layer and communicating between the internal cavity and external the covering layer;

and at least one bioactive agent disposed in the each internal cavity, the at least one bioactive agent capable of being released from within the at least one internal cavity through the at least one of a plurality of openings.

The Examiner rejected the claims as follows:

1. Claims 5-10, 15, 16, and 19-21 under 35 U.S.C. § 102(e) as anticipated by Brown (U.S. Patent 6,071,305, Jun. 6, 2000).

2. Claims 5-10 and 15-18 under 35 U.S.C. § 102(e) as anticipated by Dang (U.S. Patent 6,758,859 B1, July 6, 2004).

3. Claims 5-10 and 15 under 35 U.S.C. § 102(e) as anticipated by Wu (U.S. Patent 6,254,632 B1, July 3, 2001).

1. ANTICIPATION BY BROWN

Appellant argues the claims subject to this rejection in four groups as follows: claims 5-7; claims 8-10; claims 15 and 16; and claims 19-21. We select claims 5, 8, 15, and 19 as representative. 37 C.F.R. § 41.37(c)(1)(vii).

The Issue with Respect to Claims 5-7

Claim 5 is directed to an endoluminal stent comprising an open-ended tubular member with a luminal surface and an abluminal surface, an internal cavity within the tubular member containing a bioactive agent, and openings communicating between the cavity and the luminal and/or abluminal surfaces. There is no dispute that Brown discloses at least one embodiment, a helical stent as shown in Figures 1, 2, and 3, that meets these particular limitations of claim 5.

However, Appellant contends that the internal cavity of Brown's helical stent is not "***substantially isolated from stress or strain forces*** on the endoluminal stent during delivery," as further required by claim 5 (App. Br. 10).

The Examiner's position is that the internal cavity in Brown's helical stent is isolated from stress and strain during delivery of the stent because

"no stress/strain is applied until expansion, which occurs *after* delivery" (Ans. 10).

Thus, the issue raised by this rejection with respect to claim 5 is: Has Appellant established that the Examiner erred in concluding that the cavity in Brown's helical endoluminal stent is substantially isolated from stress and strain during delivery of the stent?

Findings of Fact

FF1 Appellant invented a "generally tubular" endoluminal stent "having cavitated regions incorporated within the material of the . . . [stent] with micropores that communicate a bioactive agent from the cavity to an area external the device" (Spec. 1: 15-17 and 26).

FF2 Claim 5 requires a stent made up of a tubular member having a central lumen where at least one internal cavity is located in a portion of the tubular member that is substantially isolated from stress or strain during delivery of the stent.

FF3 The Specification teaches that "all stents have certain structural regions that are subject to higher stress and strain conditions than other structural regions" because "stents necessarily are delivered in a reduced diametric state and are expanded or allowed to expand *in vivo* to an enlarged diametric state" so that they can serve as structural supports once in place (Spec. 5: 6-9). In other words, stents are initially biased toward a reduced state, and forced into an expanded state once in place, or they are initially biased toward an expanded state, but forced into a reduced state for delivery, and allowed to expand once in place.

FF4 According to the Specification, "it may be advantageous to position the internal cavities that retain the bioactive agents in structural regions of the stent that are subjected to relatively lower stress and strain during endoluminal delivery and deployment. Alternatively, where delivery of a bolus of a bioactive agent is desired, internal cavities may be positioned in regions that undergo large deformation during delivery and deployment thereby forcing the bioactive agent out of the internal cavity under the positive pressure exerted by the deformation" (Spec. 5: 9-15).

FF5 Further according to the Specification, internal cavities may "reside within regions of the device . . . that are substantially non-load bearing" (Spec. 12: 6-7). Alternatively, "regions . . . that are deformed or that are load bearing may include . . . internal cavities within their wall thickness and provide for elution of a bioactive agent retained within the internal cavity positioned at the load bearing region under the influence of a positive motivating pressure exerted on the bioactive agent by deformation or load stress transferred by the device geometry to the internal cavity and to the bioactive agent" (Spec. 12: 10-15).

FF6 The Specification does not explicitly identify regions that are "substantially isolated from stress or strain forces on the endoluminal stent during delivery" (as required by claim 5), but it can be inferred from the passages quoted in FF4 and FF5 that regions of the stent that undergo "large deformation" during delivery and deployment, and/or load bearing regions, are subject to higher stress and strain conditions than other structural regions, while regions that do not undergo "large deformation," or are non-load bearing, are regions that are subject to lower stress and strain.

FF7 The Specification teaches that "hinge regions . . . are load bearing regions of the stent" (Spec. 12: 8-9), thus, hinge regions are regions that are subject to higher stress and strain during delivery and deployment.

FF8 An example of a stent with internal cavities located in regions substantially isolated from stress and strain is depicted in Figure 11 of the Specification, reproduced immediately below:

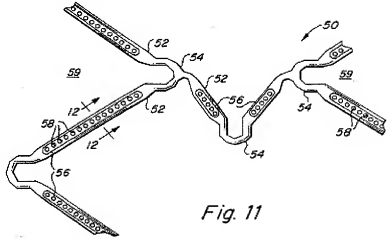

Fig. 11

Figure 11 shows a portion of an expandable stent in which "the plurality of hinge regions 54 are devoid of internal cavities 56 because they are load bearing regions of the stent" (Spec. 12: 8-9).

FF9 Brown describes a drug delivery stent **11**, an example of which is illustrated in Figures 1 and 2, reproduced immediately below:

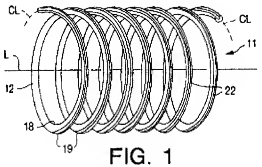

FIG. 1

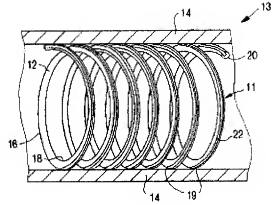

FIG. 2

Figure 1 is a perspective view of a stent **11** "formed from an elongated or tubular member **12** . . . [which] is in the shape of a coil or helix, and is expanded within a body lumen" after delivery (Brown, col. 5, ll. 39-42). Figure **2** is a cross-sectional view of a body lumen and a perspective view of stent **11** in place in the lumen (Brown, col. 3, ll. 63-65).

FF10 "The tubular or elongated member **12** of [Brown's] directional drug delivery stent **11** . . . is formed with an interior or cavity **20**, which . . . is a concave groove within the interior of the elongated member **12**" (Brown, col. 5, ll. 45-50). "[C]avity **20** contain[s] a biologically active agent for directional application" (Brown, col. 4, ll. 62-63).

FF11 "Although the cavity **20** illustrated in [Brown's] Fig. **2** is a concave groove, the interior may be other configurations and need not extend the entire length of the elongated or tubular member **12**" (Brown, col. 5, ll. 51-54). In addition, "[a]lthough the slit shaped opening **22** is illustrated, any number of fluid opening configurations may be fashioned. For example, a series or plurality of holes, grooves, small indentations, and intermittent recessions could all be fluid openings and delivery means for

directionally delivering the biologically active agent" (Brown, col. 6, ll. 13-17).

FF12 An embodiment of Brown's helical stent with the cavity on the luminal surface of the elongated, tubular member is shown in Figure **3**, reproduced immediately below:

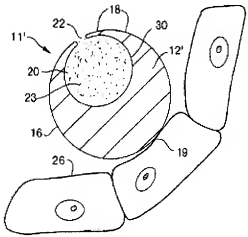

FIG. 3

Brown's Figure **3** is a "cross-sectional view of the elongated member **12´** of the stent **11´"** (Brown, col. 8, ll. 5-6), in which cavity **20** and opening **22** extend along the luminal surface of elongated, tubular member **12´**. That is, both the cavity and the opening are on the inside surface of the stent.

FF13 Brown's helical stent "has an initial diameter at which it is inserted into a body lumen, and an expanded final diameter" once in place (Brown, col. 7, ll. 26-28).

Analysis and Conclusion of Law, Claims 5-7

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

According to the Examiner, the cavity in Brown's helical stent "resid[es] within the wall thickness in portions of the tubular member that are substantially isolated from stress or strain forces . . . during delivery" (Ans. 4), at least in part because Brown's stent is delivered in an un-expanded state, and is subjected to minimal stress and strain until expansion, "which occurs *after* delivery" (Ans. 10).

Appellant contends that "Brown discloses a helical coil stent structure, where all the regions would undergo substantial stress and strain forces during delivery and deployment . . . Consequently, Brown does not contain the element recited in Claim 5 of an internal cavity substantially isolated from stress or strain forces" (App. Br. 11).

Appellant's argument is not persuasive. The Specification identifies hinge regions as regions of relatively high stress and strain during delivery and deployment (FF5, 6, 7). Brown's helical stent has no hinge regions (FF9). Nevertheless, even if we accept for the sake of argument that "all of the regions" in Brown's helical stent would undergo stress and strain at some point during delivery and deployment, the Specification distinguishes between delivery and deployment (FF3), and claim 5 merely requires isolation from stress and strain during *delivery* (FF2). Brown's stent is delivered to a location in a vessel in an initial, unexpanded state, and is expanded to its final diameter (i.e., deployed) *after* delivery (FF13).

Appellant has not established that Brown's helical stent is either load-bearing or deformed during delivery, as opposed to deployment (i.e., expansion). Therefore, Appellant has not shown that the Examiner erred in

concluding that "minimal stress/strain" is placed on the cavity of Brown's stent during delivery (Ans. 10).

The Issue with Respect to Claims 8-10

Claim 8 is directed to an endoluminal stent comprising a cylindrical member comprised of a plurality of interconnected structural elements defining walls, with a plurality of discontinuous interior cavities disposed within at least some of the structural elements.

The Examiner asserts that at least one of Brown's embodiments, an expandable "tube-type" stent as shown in Figure **18**, meets all of the limitations of claim 8, including the requirement for a plurality of discontinuous interior cavities.

Appellant contends that "Brown does not disclose 'a plurality of discontinuous interior cavities disposed completely within at least some of the plurality of structural elements', as recited in Claim 8" (App. Br. 11).

Thus, the issue raised by this rejection with respect to claim 8 is: Has Appellant established that the Examiner erred in concluding that the cavities in Brown's tube-type stent are discontinuous?

Additional Findings of Fact

FF14 Claim 8 is directed to an endoluminal stent comprising a cylindrical member comprised of a plurality of interconnected structural elements defining walls of the cylindrical member, with "a plurality of discontinuous interior cavities disposed completely within at least some of the plurality of structural elements," a plurality of openings communicating between each of the cavities and the outside of the stent, and at least one bioactive agent disposed within the cavities.

FF15 According to the Specification, "both the plurality of internal cavities 12 and the plurality of pores [i.e., openings] 14 may be positioned to be discontinuous and in different circumferential or different longitudinal regions of the tubular body 20" (Spec. 7: 21-23). In addition, "[w]ithin a single one of the plurality of interconnected structural elements 21, the internal cavities 12 may be separated by a separation member 25, which completely subtends the internal cavity 12, divid[ing] it into discrete discontinuous internal cavities 12" (Spec. 7: 23-26).

FF16 Brown describes a number of stent configurations other than the helical stent discussed above, such as "expandable tube stents, roving wire stents, and wire mesh stents. Thus the elongated member **12** may be the filaments or fibers which form a mesh stent" (Brown, col. 7, ll. 37-39).

FF17 Brown's Figures 17 and 18 show an expandable tube-type stent before and after expansion, respectively. Figures 17 and 18 are reproduced immediately below:

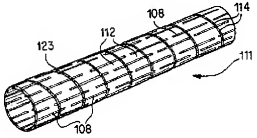

FIG. 17

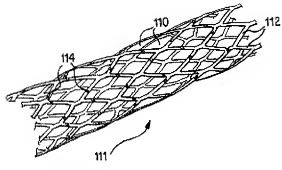

FIG. 18

Figure 17 "illustrates an example of the aforementioned expandable tube-type stent **111** . . . [Figure 18] illustrates the stent . . . in an expanded state" (Brown, col. 11, ll. 63-64).

FF18 Brown's "tube-type stent **111** is manufactured by cutting an elongated tubular member into tubular sections" (Brown, col. 12, ll. 1-2). Then, "[a] recessed active agent receiving . . . groove **120** is formed in the exterior surface **104** of the tube **102**. The groove **120** . . . is preferably a continuous helical or coiling groove extending around the tube **102** . . . the groove **120** need not be continuous" (Brown, col. 12, ll. 14-20). "Once the . . . groove **120** has been filled with active agent **123** . . . a plurality of . . . slots **108** are formed in the tube **102** . . . and extend completely through the tubular member . . . wall thickness" (Brown, col. 12, ll. 61-67).

FF19 Brown teaches that "one function of the slots is to permit the stent **111** to be expanded" (Brown, col. 13, ll. 9-10). "Because the preferred slots **108** extend longitudinally along the tube **102** and the . . . groove **120** extends helically around the tubular member, *the slots intersect the groove to define a plurality of spaced apart groove portions* **114**, each containing active agent" (Brown, col. 13, ll. 14-19 (emphasis added)). In other words, "[w]hen the tube is expanded, the tubular material between the slots **108**

forms the angled fibers or elongated members **112**, and the slots **108** form the interstitial openings **110** . . . . At least some of the elongated members **112** contain groove portions **114** or cavities in which the active agent is located" (Brown, col. 13, ll. 23-29).

FF20 Thus, Brown describes a stent with spaced apart, i.e., discontinuous, interior cavities.

Analysis and Conclusion of Law, Claims 8-10

Appellant contends that "Brown's 'plurality of cavities' in Fig. 18 does not make them discontinuous. For Claim 8, a discontinuous cavity is a *single* cavity marked by a break or interruption" (Reply Br. 9). Appellant concedes that Brown "disclose[s] a number of cavities per filament," but contends that "'Discontinuous' modifies cavity, thereby making 'discontinuous interior cavities' requiring that the cavity itself . . . be discontinuous, not the plurality of cavities to be discontinuous" (*id.*).

Appellant's argument is not persuasive. According to the Specification, the cavities may be "discontinuous" in two ways: (1) they are "positioned to be discontinuous and in different circumferential or different longitudinal regions of the tubular body" (FF15), or (2), "[w]ithin a single one of the plurality of interconnected structural elements 21, the internal cavities 12 may be separated by a separation member 25 . . . [dividing the cavities] into discrete discontinuous internal cavities 12" (FF15).

Claim 8 is not limited to the second embodiment described in the Specification where a single cavity is divided into discrete, discontinuous portions (FF14). Claim 8 merely requires "a plurality of discontinuous interior cavities disposed completely within at least some of the plurality of

structural elements" (FF14). Brown describes spaced apart grooves (i.e., cavities) disposed within different regions of the stent (FF19, 20), thereby meeting the requirement of claim 8 for discontinuous interior cavities.

Appellant has not established that the Examiner erred in concluding that the cavities in Brown's tube-type stent are discontinuous.

The Issue with Respect to Claims 15 and 16

Claim 15 is directed to a radially expandable, cylindrical endoluminal stent comprising a plurality of struts interconnected at a plurality of hinge regions. At least some of the struts are comprised of a first region "having a first wall thickness" in proximity to one of the plurality of hinge regions, and a second region "having a second wall thickness" substantially isolated from each of the plurality of hinge regions, with at least one void space formed entirely within the second wall thickness of the second region (claim 15).

Appellant contends that Brown only discloses stents with struts comprising a single wall thickness, and that Brown does not disclose "'a second region being substantially isolated from each of the plurality of hinge regions; [with] at least one void space formed entirely within the second wall thickness of the second region'" (App. Br. 13), and therefore fails to meet all the limitations of claim 15.

The Examiner asserts that claim 15 does not require the first and second thicknesses to be "two different thicknesses" (Ans. 11), nor does the claim "*exclude* . . . [void spaces] from being on the first region of the stent" (*id.*).

The issue raised by this rejection with respect to claim 15 is: Has the Examiner established that Brown anticipates the invention of claim 15 based on the broadest reasonable interpretation of the claim consistent with Appellant's Specification?

Additional Findings of Fact

FF21 The Examiner finds that Brown's expandable "tube-type" stent, shown in Figure **18**, meets all the limitations of claims 15 and 16, including the requirement for struts comprising first and second wall thicknesses, and the requirement for at least one void space formed entirely within the second wall thickness of the second region, where the second region is substantially isolated from each of the hinge regions (Ans. 5).

FF22 Appellant's claim 17, which depends from claim 15 and is not subject to this rejection, stipulates that "the second wall thickness is greater than the first wall thickness," further limiting the first and second wall thicknesses to two different wall thicknesses. Thus, claim 15 does not require the first and second wall thicknesses to be two different wall thicknesses.

FF23 According to Appellant's Specification, cavities may be located in both load bearing regions (e.g., hinge regions) and non-load bearing regions (e.g., regions isolated from hinge regions), in order to achieve the desired rate and timing of elution of the active agent(s) (Spec. 12: 18).

FF24 Claim 15 requires "at least one void space formed entirely within the second wall thickness of the second region" which is "substantially isolated from each of the plurality of hinge regions," but the claim uses the open transitional term "comprising," and is therefore not

limited to a stent with voids located *exclusively* in regions isolated from the hinge regions.

FF25 The expandable tube-type stent shown in Brown's Figures 17 and 18 (reproduced above) has "[a] recessed active agent receiving portion or groove **120** . . . formed in the exterior surface of the tube **102**" (Brown, col. 12, ll. 14-15). "Once the recessed active agent receiving portion or groove **120** has been filled with active agent **123** . . . a plurality of perforations, slits, or slots **108** are formed in the exterior surface **104** of the tube **102**, and extend completely through the tubular member thickness" (Brown, col. 12, ll. 61-67). Slots **108** "intersect the groove to define a plurality of spaced apart groove portions **114**, each containing the active agent" (Brown, col. 13, ll. 17-19).

FF26 Figure 18 (reproduced above) shows several spaced apart groove portions or recessed active agent receiving portions **114** that are formed entirely within regions that are substantially isolated from the hinge regions.

Analysis and Conclusion of Law, Claims 15 and 16

"[D]uring examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification." *In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000).

> [T]he PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification.

In re Morris, 127 F.3d 1048, 1054 (Fed. Cir. 1997). However, the claims are not to be confined to the embodiments found in the Specification, and it is improper to import limitations from the Specification into the claims. *In re Trans Texas Holdings Corp.*, 498 F.3d 1290, 1299 (Fed. Cir. 2007).

Appellant contends that Brown does not disclose "two different wall thicknesses" as required by claim 15 (App. Br. 13).

This argument is not persuasive. Claim 15 does not require that the first and second wall thicknesses are different (as opposed to narrower dependent claim 17, which does) (FF22).

Appellant contends that "Brown's Fig. 18 . . . clearly shows groove portions 114 [that] intersect with or are immediately adjacent to . . . hinge regions of the stent struts 112 . . . Thus, it cannot be said that the groove portions 114 are ***substantially isolated from each*** [and every] of the plurality of hinge regions, as claimed" (App. Br. 13, 14).

This argument is not persuasive. Claim 15 merely requires "at least one void space formed entirely within the second wall thickness of the second region" which is "substantially isolated from each of the plurality of hinge regions," and the open language of the claim does not preclude voids located in the hinge regions as well (FF24) Moreover, this interpretation of the claim is consistent with the Specification, which teaches that cavities (i.e. void spaces) may be located in both load bearing regions (e.g. hinge regions), as well as non-load bearing regions, depending on the desired elution profile (FF23).

Finally, Appellant argues that groove space 114 "is not a 'void space formed entirely within' a second wall thickness . . . [because] the groove

portions 114 open not only at their upper opening, but the end openings defined in the stent struts become exposed to the exterior of the wall thickness of elongated members 112 . . . [and] the open surface of the groove 123 changes as the stent is radially expanded" (App. Br. 14).

This argument is not persuasive. Brown's grooves are located in the walls of the struts. Appellant has not identified anything in the Specification which supports his restrictive definition of "a void space entirely within" the wall thickness.

The Examiner has established that Brown anticipates the stent of claim 15, based on a reasonable interpretation of the claim consistent with the Appellant's Specification.

The Issue with Respect to Claims 19-21

Claim 19 is directed in part to a drug eluting stent comprising a plurality of metal strut members interconnected by a plurality of hinge regions. The claim requires a generally U-shaped metal covering layer with a plurality of openings formed in it, disposed over the intermediate regions between adjacent hinges of at least some of the struts, defining an internal cavity therebetween.

The Examiner asserts that the requirement for a U-shaped metal covering is met by "portion 19" of Brown's drug eluting stent (Ans. 6).

Appellant contends, at least in part, that "portion 19 is a portion of the circumference of the elongated member . . . [and] is not a layer as to anticipate Claim 19's metal covering layer" (App. Br. 16).

The issue raised by this rejection with respect to claim 19 is: Has the Examiner provided an adequate factual basis to support her conclusion that Brown discloses a stent with a U-shaped metal covering?

Additional Findings of Fact

FF27 The Examiner asserts that the required U-shaped "metal covering layer may be considered to be [the] top layer of the stent 19, . . . [as shown in] fig. 4, 6 for example" (Ans. 6).

FF28 Brown's Figure 4 is reproduced immediately below:

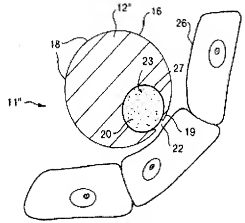

FIG. 4

Figure 4 is a cross-sectional view of the elongated member **12"** of a stent **11"** which "directionally delivers the biologically active agent **23** from the cavity **20** and through the slit opening **22**, which is located at the support portion **19** of the outer surface **16**, such that the biologically active agent is delivered to the body lumen wall **26**" (Brown, col. 8, ll. 55-60).

FF29 Elongated member **12"** can form the struts of a mesh stent (FF21), however, support portion **19** is an integral part of elongated member **12"**, and is not a U-shaped metal layer covering portion of the elongated member/strut **12"**.

Analysis and conclusion of Law, Claims 19-21

> The Patent Office has the initial duty of supplying the factual basis for its rejection. It may not, because *it* may *doubt* that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in its factual basis. To the extent the Patent Office rulings *are* so supported, there is no basis for resolving doubts against their correctness. Likewise, we may not resolve doubts in favor of the Patent Office determination when there are deficiencies in the record as to the necessary factual bases supporting its legal conclusion . . .

In re Warner, 379 F.2d 1011, 1017 (CCPA 1967) (emphasis in original). *Warner* concerned the factual basis of an obviousness rejection, but its central premise is equally appropriate here.

Even if we accept, for the sake of argument, that Brown's support portion **19**, which is an integral part of elongated member/strut **12"** (FF29), is a "covering layer" forming a cavity between the strut and support portion **19**, the Examiner has not pointed to anything in Brown which shows that it is U-shaped.

Thus, the Examiner has not provided the factual basis necessary to support her conclusion that Brown discloses a stent with a U-shaped metal covering.

Decision with Respect to Anticipation by Brown

We affirm the rejection of the claims under 35 U.S.C. § 102(e) as anticipated by Brown with respect to claims 5-10, 15, and 16, but reverse the rejection with respect to claims 19-21.

2. ANTICIPATION BY DANG

The Examiner rejected claims 5-10 and 15-18 under 35 U.S.C. § 102(e) as anticipated by Dang.

The Issue

The Examiner's position is that Dang describes an endoluminal stent comprising a tubular member that meets all of the limitations of claims 5-10 and 15-18, including the requirement for "a plurality of openings communicating between the at least one internal cavity and at least one of the luminal surface, abluminal surface, proximal end or distal end of the tubular member" (claim 5); the requirement for "a plurality of openings communicating between each of the . . . interior cavities and external the stent" (claim 8); and the requirement for "a plurality of pores communicating between the at least one void space [formed entirely within the wall of the stent] . . . and external the endoluminal stent" (claim 15).

Appellant contends in part that Dang does not teach or disclose a "***plurality of openings***" or a "***plurality of pores***" communicating between any single internal cavity or void space in the wall of the stent and the exterior of the stent (App. Br. 21, 23), as required by all the claims subject to this rejection. In other words, Appellant contends that Dang discloses only a "***single opening***" per cavity or void space (*id.* at 21).

Thus, the issue raised by this rejection with respect to claims 5-10 and 15-18 is: Has the Examiner provided an adequate factual basis to support her conclusion that Dang discloses a stent with a plurality of openings or pores communicating between an internal cavity or void and the surface of the stent?

Findings of Fact

FF30 All of the claims subject to rejection over Dang require a plurality of openings or pores communicating between a single internal cavity or void, residing or disposed within the wall thickness or structural elements of the stent, and the exterior of the stent. That is, all of the claims require more than one opening or pore per cavity or void. Moreover, the luminal surface of the stent is not a cavity or void residing or disposed within a wall thickness or structural element of the stent.

FF31 Dang describes a cylindrical or tubular expandable "prosthesis, one example of which includes a stent . . . The outer surface of the prosthesis is capable of contacting an inner lumen surface of a passageway. In addition, the body structure of the prosthesis has one or more elements having a width and a thickness. The width of the element(s) is variable from a nominal or conventional width to an increased width" (Dang, col. 2, ll. 41-51).

FF32 Dang's "variable width prosthesis includes one or more depots formed on the elements of the prosthesis. The depots have an open end, a closed end, a diameter and a depth that is less than the thickness of the body structure of the prosthesis. In general, the depots are formed at the increased width sections of the elements" (Dang, col. 2, ll. 52-58).

FF33 "The depots **30** are formed to carry . . . therapeutic substances" (Dang, col. 5, ll. 10-11), and the depth, diameter, and quantity of the depots, as well as their location on the elements **22** of the stent, varies according to intended usage and application (Dang, col. 6, ll. 24-27; col. 8, ll. 29-30).

FF 34 Dang's Figures **5***a* and **5***b*, reproduced immediately below, show cross-sectional and top views of "a plurality of depots on a surface portion" of a stent (Dang, col. 3, ll. 20-23):

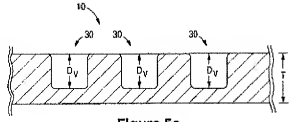

Figure 5a

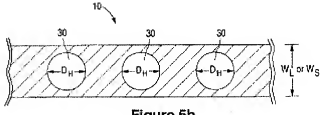

Figure 5b

Figures **5***a* and **5***b* illustrate cross-sectional and top views of individual depots **30** for therapeutic substances.

FF35 While Dang's stent has a plurality of depots, and "depot configurations . . . can include . . . tear-drop shaped, cubic shaped, spherically shaped, and other configurations and shapes" (Dang, col. 6, ll. 60-63), none of the depots described by Dang has more than one opening per depot.

Analysis and Conclusion of Law

All of the claims subject to this rejection require a plurality of openings or pores per cavity or void (FF30), not merely a plurality of openings or pores in the stent as a whole.

The Examiner asserts that Dang describes a stent with "a plurality of openings (open end is considered an 'opening' . . . [and] the cavities may be

any shape, including shapes such as tear drop, wherein the opening is smaller that the cavity . . .) communicating between the at least one internal cavity (30) and at least one of the luminal surface, abluminal surface, proximal end, or distal end of the tubular member (fig. 5a)" (Ans. 7).

We agree with Appellant that "no single depot 30 disclosed in the Dang reference contains a 'plurality of openings', i.e., more than one opening . . . [and] [a] tear drop opening still only contains a ***single opening***" (App. Br. 21).

Thus, the Examiner has not provided an adequate factual basis to support her conclusion that Dang discloses a stent with a plurality of openings or pores communicating between an internal cavity or void and an exterior surface of the stent.

Decision

We reverse the rejection of claims 5-10 and 15-18 under 35 U.S.C. § 102(e) as anticipated by Dang.

3. ANTICIPATION BY WU

The Examiner rejected claims 5-10 and 15 under 35 U.S.C. § 102(e) as anticipated by Wu.

The Issues

Appellant contends, among other things, that "Wu does not disclose 'a plurality of openings communicating between the at least one internal cavity and at least one of the luminal surface'" as required by claims 5-7 (App. Br. 27), or "a plurality of discontinuous interior cavities disposed completely within at least some of the plurality of structural elements" (*id.* at 28) with "a plurality of openings communicating with an internal cavity and external the

stent" as required by claims 8-10 (*id.* at 29); or "a 'void space formed entirely within the second wall thickness' of a strut region" as required by claim 15 (*id.*).

The Examiner's position is that "Wu discloses a stent . . . comprising a structural member (104, 102) and cover member (420) and a cavity (area occupied by agent 410 . . .) therebetween, and a plurality of openings (openings in porous polymer cover 420) passing through the cover member" (Ans. 9).

The issues raised by this rejection are: Has the Examiner provided an adequate factual basis to support her conclusion that Wu discloses a stent with a plurality of openings or pores communicating between an internal cavity and the surface of the stent, and that Wu describes a stent with cavities or void spaces formed entirely within the structural elements or struts of the stent, with a plurality of openings communicating between the cavities or void spaces and the exterior of the stent?

Additional Findings of Fact

FF36 Wu describes "protruding structures . . . [on] the surface of a stent . . . [which] can be used with covered stents . . . to engage and secure the cover, . . . to keep glue in place on the stent when attaching the covering. The protruding structures can also be used to deliver therapeutic substances from the stent directly to the lumen wall" (Wu, col. 2, ll. 53-62).

FF37 "An exemplary protruding structure includes a depression region having a bottom surface that is fully or partially surrounded by a protruding lip . . . [that] is higher than the bottom surface relative to the surface of the stent" (Wu, col. 2, l. 64 to col. 3, l. 2).

FF38 Wu's Figure **2**B is reproduced immediately below:

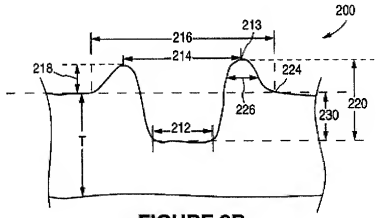

FIGURE 2B

Figure **2**B "is a cross-sectional side view of a portion of a stent strut with a crater that has a bottom surface recessed beneath the stent surface" (Wu, col. 3, ll. 46-48).

FF39 Wu's Figure **4**A is reproduced immediately below:

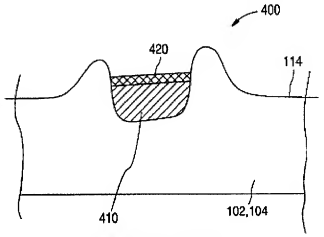

FIGURE 4A

Figure **4**A is a cross-sectional side view of a "protruding structure[ ] that contain[s] a therapeutic substance . . . covered by a polymeric layer" (Wu, col. 3, ll. 63-65).

FF40 The Examiner describes polymeric layer **420** as "porous" (Ans. 9), but does not point to anything in Wu which indicates that the polymer actually is porous. Wu merely describes the "[p]olymeric materials that can be used for layer **420**, **430** . . . [as] either bioabsorbable or biostable" polymers which "are gradually absorbed or eliminated from the body by hydrolysis, metabolic process, bulk or surface erosion" (Wu, col. 6, ll. 37-43).

FF41 The Examiner's assertion that Wu's polymer layer **420** meets the claims' requirement for a plurality of openings per cavity or void space is not supported by Wu's description of the polymer layer.

Analysis and Conclusion of Law

While Wu's stent has a plurality of cratered structures, the structures, including the craters, protrude at least partially from the surface of the stent (FF 36-39), thus none of the craters (i.e., cavities or voids) is "disposed completely within" or "formed entirely within" a structural element or strut (as required by claims 8-10 and 15). Moreover, none of the protruding structures has more than one opening per crater (as required by claims 5-10 and 15) (FF40, 41).

The Examiner has not provided an adequate factual basis to support her conclusion that Wu discloses a stent with a plurality of openings or pores communicating between an internal cavity and the surface of the stent as required by claims 5-7, or that Wu describes a stent with cavities or void spaces formed entirely within the structural elements or struts of the stent (as required by claims 8-10 and 15), with a plurality of openings communicating

between the cavities or void spaces and the exterior of the stent (as required by claims 5-10 and 15).

Decision

We reverse the rejection of claims 5-10 and 15 under 35 U.S.C. § 102(e) as anticipated by Wu.

SUMMARY

The rejection of claims 5-10, 15, 16, and 19-21 under 35 U.S.C. § 102(e) as anticipated by Brown is AFFIRMED with respect to claims 5-10, 15, and 16, but REVERSED with respect to claims 19-21.

The rejection of claims 5-10 and 15-18 under 35 U.S.C. § 102(e) as anticipated by Dang is REVERSED.

The rejection of claims 5-10 and 15 under 35 U.S.C. § 102(e) as anticipated by Wu is REVERSED.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED-IN-PART

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